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BREAST CANCER DETECTION: THE NEED FOR A FEDERAL RESPONSE

F 136 ORIGINAL

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

AND THE

TASK FORCE ON SOCIAL SECURITY AND WOMEN

OF THE

SELECT COMMITTEE ON AGING
HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

FIRST SESSION

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BREAST CANCER DETECTION: THE NEED FOR A FEDERAL RESPONSE

WEDNESDAY, OCTOBER 23, 1985

HOUSE OF REPRESENTATIVES, SELECT COMMITTEE ON AGING, SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE AND TASK FORCE ON SOCIAL SECURITY AND WOMEN,

Washington, DC.

The subcommittee and task force met, pursuant to notice, at 10 a.m., in Room 2359-A, Rayburn House Office Building, Hon. Claude Pepper (chairman of the subcommittee) and Hon. Mary Rose Oakar (chairwoman of the task force) presiding.

Members present: Representatives Pepper, Oakar, and Bentley.

Staff present: Kathleen Gardner Cravedi, staff director; Melanie Modlin, assistant staff director; Peter Reinecke, research director; Patricia Butch, congressional fellow; Karen Wedding, intern; Mark Benedict, minority staff director; Patrick McCarthy, detailee, of the Subcommittee on Health and Long-Term Care; and Karen Pollitz, legislative assistant to Ms. Oakar.

OPENING STATEMENT OF CHAIRWOMAN MARY ROSE OAKAR

Ms. OAKAR [acting Chair]. The Subcommittee on Long-Term Care and Health of the Select Committee on Aging will come to order.

The chairman of the committee, the distinguished Senator Claude Pepper, is on his way here. In the interest of time, I would like to begin.

I am very pleased that our committee is holding this hearing this morning. I want to applaud my friend and colleague Congressman Claude Pepper, and I greatly appreciate his efforts and those of all the very fine witnesses that we have today in developing this hearing. I am especially grateful to my personal staff for all the hard work they have put in, and the staff director and others who work so hard for the Aging Committee.

This hearing coincides with Breast Cancer Awareness Week, and raising public awareness is what we are all about today. Breast cancer is a national tragedy, a leading killer and crippler of women today. As we speak, more than 1 million women living in this Nation are being treated or have been treated for breast cancer. Every year more than 100,000 additional women will develop this disease. In all, breast cancer will strike 1 out of every 11 women at some point in their lives.

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I might add that breast cancer affects six times more people than AIDS, for example, which is also a disease that we are very concerned about.

Breast cancer is also a major cause for health spending. In 1984 Americans spent $2 billion on hospital, physician and other medical services associated with the treatment of breast cancer. Of that total, Medicare paid more than $400 million. These costs do not include lost wages, disability payments by employers, or other economic losses to families that occur when breast cancer strikes. Nor do they even remotely reflect the emotional toll taken when one's mother or sister or spouse is threatened by the disease.

The high incidence and high cost are not the only terrible statistics associated with breast cancer. The breast cancer mortality rate has really not changed since 1950, even though deaths from other major causes, including heart disease, liver disease, diabetes, and automobile accidents, have declined. In 1950, for example, there were 22.2 breast cancer deaths per 100,000 population, and today the figure is 22.8 per 100,000. In this day of medical miracles and technological wizardry, continued deaths from breast cancer are horrifying. They are even more so because no woman should have to die of breast cancer. Medical research has shown that, when detected in its earliest stages, breast cancer can be treated with limited nondisfiguring surgery and radiation therapy and other kinds of therapy, and is almost completely survivable. Yet, the screening procedure, mammography, that can detect breast cancer in most cases is not covered by Medicare, is not covered by most private insurance, and thus is not an affordable option for most individuals.

Screening for breast cancer must be made more affordable and must be more widely available. Such a change would prove cost-effective and would save lives. The most recent issue of Business and Health magazine cites a study estimating the average cost of treating late-stage breast cancer to be $60,000, compared to only $18,000 when it is detected in an early stage. Thus, up to 70 percent of what we spend for the treatment and care of breast cancer patients could be saved with early detection.

During this Congress, I have introduced legislation—I am pleased that my chairman of my committee has been a major supporter—H.R. 1402, which would establish a voluntary option under Medicare to pay for preventive health care including mammography screening for breast cancer. This preventive care insurance option is structured so that it will not increase costs either to Medicare or to senior citizens. Under my bill, Medicare would offer a Federal version of medifill insurance, a policy that most Medicare enrollees now purchase to cover their deductibles and copayments. Medicare's medifill, however, could be offered at a much lower administrative cost, with the savings used to pay for preventive care. Thus, enrollees could purchase a policy for the premiums they currently pay and receive the added benefit of coverage for annual checkups, including mammography screening.

I firmly believe that prevention and health maintenance are as crucial after the age of 65 as they are in earlier ages. Among the breast cancer victims, one third of whom are over age 65, Medicare coverage for screening will lead to early detection, will save lives

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and, frankly, it will save an awful lot of money and emotional toll as well.

Also in this Congress I have introduced a prevention bill of another sort, H.R. 1579, the Breast Cancer Treatment Informed Consent Act of 1985. This would require States to enact laws requiring physicians to inform their breast cancer patients orally and in writing of all the viable treatment options facing them before treatment begins. Consequently, patients would have the benefit of more complete information and a greater say in the determination of what will happen to them when they develop breast cancer. Without information, many breast cancer patients are victimized by fear that can hinder them from seeking treatment in the first place. More complete knowledge can prevent some of the terror as well as unwanted or unnecessary surgery.

We have very distinguished witnesses that will testify today about the studies that they have conducted and the varieties of success stories and options that women really do have in the treatment of this disease.

Ultimately, of course, I believe that total prevention through the development of vaccine is the solution to the tragedy of breast cancer. I really believe that it is a national tragedy. It is not in a partisan way that I say this. But it is a national tragedy that in the last 10 years we have decreased the Government money that we put into cancer research. We have absolutely escalated the amounts of taxpayers' money that we use for weapons of violence. To me, that is one of the sad ironies.

I believe that if our country made a national commitment to find a cure for cancer, we could do it. I honestly believe that, if we had the American will behind curing a disease that afflicts every family, just about every family, including my own, in the United States we would lick breast cancer and other forms of cancer. But we have to have the American will to do it, the same kind of will that goes into spending billions of dollars in other areas.

So, I am really pleased that during this Breast Cancer Awareness Week we have such very, very distinguished people who are our witnesses. Some of the people who are here, in fact all of them, have personally sacrificed at their own expense to be here. Before we hear from them, I have some material I would like to submit for the hearing record.

The first item I wish to submit is a subcommittee briefing paper entitled, "Breast Cancer Detection: The Need for a Federal Response." Hearing no objections, so ordered.

[The briefing paper submitted by Representative Oakar follows:]

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"BREAST CANCER DETECTION: THE NEED FOR A FEDERAL RESPONSE"
OCTOBER 23, 1985
A BRIEFING PAPER
U.S. HOUSE SELECT COMMITTEE ON AGING
SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

Introduction

Cancer is of great concern to the people of the United States and to people worldwide, and rightfully so. While we have made tremendous strides in treatment, we still have no solution, no cure, for this deadly disease.

Cancer is of special concern to the elderly people of this country, who are far more vulnerable than younger segments of the population. Persons over 54 years of age constitute 81 percent of all cancer deaths, and as you know, over 400,000 people each year die of cancer. People over the age of 65 account for 60 percent of all cancer deaths.

The subject of today's hearing, breast cancer, is currently an epidemic in this country. This dreaded disease claims the life of one American woman every 15 minutes. Breast cancer is of particular concern to our elderly, especially our elderly women. One-quarter of the estimated 38,000 American women who will die of breast cancer in 1985 will be over the age of 75. An additional 120,000 new cases of the disease will be diagnosed in the United States this year, according to estimates from the National Cancer Institute. Breast cancer is an epidemic in the United States — 1 out of every 11 women will get it at some point in their lives. And over 1 1/2 million women have or have had breast cancer in the United States today. Practically every family has, unfortunately, been affected by this disease, which is one of the most serious health problems that we have among women in our country.

Last year the Subcommittee on Health and Long-Term Care convened a hearing on "Progress in Controlling Breast Cancer." This hearing explored what is known about breast cancer and what might be done to reduce its devastating death toll. We found that, if the disease is detected earlier, breast cancer surgery need not be so radical, and that survival rates can be substantially increased — by about 30 percent — saving 10,000 lives annually. In spite of these encouraging Subcommittee findings, we were shocked to learn that death rates associated with breast cancer have not declined in the past 50 years.

In an effort to determine why known early detection technologies have not led to a saving of lives in the United States, Subcommittee Chairman Claude Pepper undertook a national review of the problem. In the course of the Subcommittee investigation, the following steps were taken:

- a review of all books, periodicals and newspaper references to breast cancer in the possession of the Library of Congress;
- at the Chairman's request, a telephone survey by the Subcommittee of all 51 State chapters of the American Cancer Society, to determine what early screening and mammography clinics were in existence, serving communities around the states;
- at the Chairman's request, a telephone survey of all 51 State Departments of Health, to determine what early screening and mammography clinics were in existence, serving communities around the states;
- the commissioning of a report by the Congressional Research Service on recent clinical trials on treatment and prevention, as well as public and private initiatives to educate the general public on breast cancer;
- conferring with officials at the National Cancer Institute, National Institutes of Health, to attempt to gauge developments in Federally funded programs for breast cancer detection;
- conferring with officials at such private cancer associations as the American Cancer Society and the National Cancer Foundation, to attempt to gauge developments in privately funded programs in breast cancer detection;
- contacting the American College of Radiology to ascertain advantages of mammography and other types of breast cancer screening;
- speaking with physicians renowned for their work in breast cancer, to gain their views on developments in detection and their suggestions for reform; and
- contacting numerous self-help, volunteer groups that work with the victims of breast cancer and their families.

The Subcommittee found that, despite 30 years of research by the National Cancer Institute

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(NCI) which resulted in findings that deaths from breast cancer can be reduced by some 30 percent annually through known detection techniques like mammography, little is being done at the Federal level to promote the application of these techniques.

Congressional Research Service Report Findings

At the request of Chairman Pepper, the Science Policy Research Division, Congressional Research Service, prepared a 43-page report on breast cancer. Limited space prohibits including this report here in its entirety. However, the full report will be added to the Subcommittee hearing record, and a summary of findings follows.

Breast cancer is the most common cause of cancer death for women in North America and most of Europe. Despite new approaches to treatment and diagnosis, death rates have not changed significantly in the last 50 years.

Epidemiologists have identified a number of risk factors, which will be discussed in detail below. Gender is the single most important risk factor in breast cancer. While 1 in 11 women are stricken by the disease, males are affected at only one one-hundredth that rate. The risk of breast cancer increases with age up until middle age. Eighty percent of breast cancer cases occur in women over 50.

Despite the identification of numerous risk factors associated with breast cancer, including heredity, time of the first menstrual period, and exposure to high doses of radiation, the exact cause or set of causal factors remains unknown. The development of breast cancer probably results from complex interactions between a variety of factors including genetic predisposition, hormone levels, immune system activity, diet, and possibly exposure to particular viruses, carcinogens and radiation.

With regard to detection, it has been noted that 75 to 90 percent of all breast cancers are detected by the woman herself, usually by accident. Because of this, the American Cancer Society has for years advocated breast self-examination, usually on a monthly basis. However, few women actually practice BSE on a regular basis, and those who do correctly identify breast cancer only 35 to 50 percent of the time. In spite of this, several studies have shown that there is a benefit in terms of earlier disease detection, although no studies have clearly shown a benefit from breast self-examination in terms of reducing mortality.

A breast lump discovered by either the patient or her physician carries a 20 percent risk of cancer, and therefore further tests are necessary to determine a diagnosis. A mammogram (discussed in full below) may be ordered to distinguish a cancerous from a benign tumor. Mammography utilizes x-rays to bring up a visual image of the breast's internal structure.

A diagnosis of breast cancer is confirmed by removing cells or tissue and examining them under a microscope. When a breast mass is suspected of being a fluid-filled cyst, fine needle biopsy (aspiration) is often performed under local anesthesia. The acceptance of aspiration as a diagnostic technique has been helpful in moving the site of diagnosis from the operating table in the hospital to the physician's office, thus allowing the patient an opportunity to voice an opinion on whether or not further surgery is desired. It is now generally thought that a delay of a few days or weeks between diagnosis and treatment does not involve an increase in risk to the patient.

After removal, the fluid may be examined by a cytologist for the presence of cancer cells. If the lump disappears after aspiration, no further treatment may be required. If the lump remains or the fluid contains cancer cells, a second biopsy, in which surrounding tissue is removed, may be performed. About 75 to 80 percent of the time the microscopic diagnosis of the removed tissue indicates a benign tumor. However, microscopic analysis is not always accurate. Approximately 30 percent of all lesions thought to be cancer are not, and 15 percent of those believed benign turn out to be malignant.

Mammography, in which x-rays are used to visualize the internal structure of the breast, is the most effective tool currently available to detect nonpalpable breast cancer.

In 1973, the National Cancer Institute and the American Cancer Society initiated the Breast Cancer Detection Demonstration Project. Over 280,000 women aged 35 to 74 were recruited and examined using mammography, in an attempt to demonstrate to the medical community and the general public the feasibility of screening large numbers of women for the early detection of breast cancer.

Mammography was highly praised as a method of detection. Of the 3,557 cases detected by screening, 42 percent were found only by mammography. The results were particularly impressive for very tiny lumps, less than one centimeter. For some time, a cloud of controversy surrounded this technique, because of possible risks posed by radiation. More detailed information on the low risk associated with mammography appears later in this paper.

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The extent of disease at the time of diagnosis is the most important factor in determining the patient's prognosis. Depending on size, clinicians classify the tumor as being either Stage I (smallest), Stage II, Stage III or Stage IV (largest). The higher the stage, the poorer the prognosis. The five-year survival rates of the four stages are 85 percent, 66 percent, 41 percent, and 10 percent respectively.

Breast cancer treatment has undergone dramatic changes since Halsted first described radical mastectomy — the removal of the entire breast, skin, chest muscles, and lymph nodes — in 1896. By the late 1940s, doubts began to be expressed whether the radical mastectomy was necessary for every patient. Surgeons were seeing patients at a much earlier stage than in Halsted's day when many patients had large ulcerated masses. Their research suggested that survival was not improved by extensive operations. The removal of the breast, without disturbing the axillary nodes and pectoral muscles, became the technique of choice. This is called total, or simple, mastectomy.

In the 1960s, there were reports advocating the simple removal of the breast tumor (lumpectomy) followed by radiation. Another method of treatment, segmental mastectomy, removes the entire tumor plus enough breast tissue to ensure that the remaining tissue in the patient is free of disease. Studies by the NCI in 1976 indicated total mastectomy provided no improved treatment results over segmental mastectomy. In fact, disease-free survival after segmental mastectomy was better than disease-free survival after total mastectomy,and overall survival after segmental mastectomy, with or without radiation, was better than overall survival after total mastectomy.

Chemotherapy and hormone therapy are other avenues of breast cancer treatment now being explored. These are being employed as "adjuvants," or enhancers, to reduce the size of the breast tumor before radiation therapy or surgery. The use of adjuvant systemic therapy in breast cancer is relatively recent, and certainly the object of much dispute. Extensive testing of this type of therapy is now underway in the United States and several other countries. On September 9-11, 1985, the National Institutes of Health held a Consensus Development Conference on adjuvant chemotherapy for breast cancer. As it had done at the first such conference in 1980, the panel recommended that all eligible women with breast cancer participate in clinical trials.

The study of breast cancer is a very rapidly evolving area of research. Over the last several years, there have been major changes in the general consensus within the medical and research communities on various aspects of this disease. A new understanding of tumor biology and the gradual recognition that even early breast cancer is often a systemic disease has brought changes in ideas about screening and treatment.

- Early detection through screening does not guarantee cure, although patient survival rates are much higher when the tumor is small.

- The Halsted radical mastectomy has been replaced for the most part by less extensive surgical procedures. The benefits of less extensive surgery over radical mastectomy are improved physical appearance, physical capacity and psychological well-being.

Because the cause or causes of breast cancer have not been identified, prevention is not possible at the present time. Various factors have been associated with an increased risk for developing breast cancer, and these include sex, age, family history, reproductive experience, previous benign breast disease, radiation and diet. Through further research, it is hoped that the cause of breast cancer can be defined. Using this knowledge, better methods of prevention and treatment could then be developed. For now, early detection of breast cancer seems one hopeful step women can take.

(The Subcommittee would like to thank Judith A. Johnson of the Science Policy Research Division for her work on this paper and for other information. Vikki A. Zegel, also with the Congressional Research Service, made important contributions to this hearing, too.)

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Questions and Answers

The following section is designed to provide answers to some of the most frequently a questions about breast cancer.

Q. What is breast cancer?

A. Breast cancer is a disease caused by uncontrolled growth of abnormal cells in the tissue of the breast.

Q. Who is at risk?

A. Gender is the single most important risk factor in breast cancer; males are affected at only one hundredth the rate of females.

In 1985, approximately 38,000 American women will die from breast cancer and an additional 120,890 new cases of the disease will be diagnosed in the United States, according to the National Cancer Institute's estimates. Breast cancer affects one woman in 11 in the United States and has been the leading cause of death from malignancy among women. The disease claims the life of one American woman every 15 minutes. Worldwide, breast cancer is diagnosed in over 1 million women annually.

Some women may be at higher risk than the general population for developing breast cancer. They include women who have several of the following characteristics:

- over 50 years of age
- with a family history of breast disease
- who have never had children
- who had their first child after 30
- with a family history of benign breast disease
- who began menstruating before age 12
- who began menopause after age 50
- more than 10 percent overweight
- have a high fat intake, which may affect estrogen metabolism, an imbalance of which is associated with increased risk of certain cancers, e.g. breast cancer.

However, even women who don't fit into these categories should still take care to perform monthly self-examinations, request breast examination by a health care provider, and seek low-dose mammography as appropriate (see below).

Q. Can breast cancer be prevented?

Breast cancer can't be prevented, but its spread can be controlled through earlier detection techniques such as regular breast self-examination, regular physician examinations, and low-dose mammography.

Q. What are the advantages of early detection of breast cancer?

Chances for survival are greatly improved when breast cancer is detected at an early stage and treated appropriately. Fifty years of research indicate that breast cancer deaths can be reduced by 30-40% annually through earlier detection, and that less radical surgical intervention is often required.

Q. What are the barriers to early detection?

A. The Subcommittee found that the reasons so many women do not receive the benefit of detection or new preventative technology are directly related to the awareness, the affordability, and the availability of screening and detective procedures.

First, most women are not aware of screening techniques available to them which, if employed, could substantially their risk of a devastating bout with breast cancer or minimize surgical intervention required to halt its progress. American women need to be informed of the choices that are available to them to become a "partner" in detecting and treating breast cancer. The fear that "choices" are unavailable steers many women away from seeking routine screening for breast cancer.

Second, women frequently cannot afford most preventative measures currently available for earlier detection and treatment of breast cancer. Medicare will not pay for most preventative services, like early detection of breast cancer or other cancers. In addition, a 1984

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Subcommittee survey found that the top 50 insurance companies in the United States do not reimburse women for breast cancer screening tests unless women are symptomatic or have a history of breast cancer in their family. By the time symptoms are detectable, it is often too late.

Third, we found that for those women who do want to take preventative measures — to get screened regularly and obtain less radical surgical intervention — availability of screening and detection centers — outside of a hospital setting requiring physician referral — is almost nonexistent. Those screening and detection centers in existence are often difficult to locate. The majority of State Health Departments knew little about State efforts in breast cancer detection. About 60% of the State Health Departments knew of absolutely nothing in the way of low-cost screening of any sort for breast cancer.

Ironically, too, the later the disease is detected, usually the greater the expense incurred for treatment.

Q. What are the three most common forms of screening? How much do these cost and how frequently should they be performed?

A. Breast self-examination (BSE): This is a procedure whereby a woman examines her own breast at about the same time every month, to identify any changes, thickening of tissue, lumps in the breast or discharge from nipples. By performing this examination for herself every month, a woman can become familiar with what is "normal" for her and can assure consistent monitoring of breast health between physical examinations. Many pamphlets and classes are available to teach a woman breast self-examination. Obviously no costs are involved and information on BSE can be obtained through American Cancer Society chapters.

Physical examination: A physical examination is a thorough palpitation of a woman's breast by a health care provider. It is helpful if this breast exam is a regular component of the woman's annual check-up, although at-risk women may want to have the examination performed with greater frequency. The costs for a physical exam vary by physician and region.

Mammography: Mammography uses x-rays to visualize the internal structure of the breast and to create an image of the breast on film. A mammography can detect cancers that are too small to be felt by a woman with manual examination, and this can improve survival rates. A baseline mammogram, taken as a screening tool when no symptoms are present, can be helpful for later comparison. Costs for mammography range from $25, at the Guttman Clinic in New York (decidedly the exception and not the rule), to a high of $323, with most falling in the $100-150 range.

Q. What are the risks associated with mammography? The benefits?

A. In recent years, the body of medical opinion on this subject has changed considerably. Risks for mammography screening were those of low level radiation. New data indicate these are minimal enough to be undetectable, if the mammography is conducted in a safe, regulated way and equipment is modern. The benefit of such screening is a reduction in breast cancer mortality. Evidence indicates that the small cancers detected by mammography are true malignancies rather than premalignant lesions. Therefore, earlier detection increases the number curable.

Q. How often and at what age should a woman receive a mammography?

A. Opinions on recommended schedule vary:

The American College of Radiology: For asymptomatic women, the first, or baseline, mammogram should be obtained by age 40. An earlier age is preferable when there is a personal history of breast cancer or a history of premenopausal breast cancer in the patient's mother and/or sisters. Subsequent mammographic examinations should be performed at one or two year intervals determined by the combined analysis of physical and mammographic findings and other risk factors, unless medically indicated sooner. Annual mammography and physical examination are recommended for all women over age 50.

The American Cancer Society recommends monthly breast self-examination starting at age 20; physical examination of the breast at three-year intervals between the ages of 20 and 40, and annually thereafter; a baseline mammogram between the ages of 35 and 40, followed by annual or biennial mammograms from 40 to 49, and annual mammograms from 50 on.

The American College of Obstetricians and Gynecologists maintains that women over the age of 50 should receive regular breast examinations including mammography at intervals to be determined by the physician. For women between the ages of 35 and 50, it is recommended that a "baseline" mammogram be done in connection with a clinical examination. From the results of

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[illegible] palpation and other examinations, the physician should determine the frequency of mammography.

Q. What is the Federal government doing to encourage early detection?

A. The Subcommittee found that the National Cancer Institute (NCI) is largely responsible for what is now known about the early detection and treatment of breast cancer today. Major research undertakings over the last 30 years by the NCI have resulted in the Subcommittee's awareness that, if detected earlier, breast cancer surgery need not be so radical and survival rates can be substantially increased. Given these impressive findings by NCI, the Subcommittee was shocked to review the NCI's efforts to demonstrate the effectiveness of early detection and screening. Of the 3,000 grants and contracts currently supported by the NIC, only 3 are related specifically to "improvements" in breast cancer screening. None provides for the dissemination of information on screening to the American public.

Q. What are the Subcommittee's recommendations for reform?

A. — Better health education of women, health care providers, and involved agencies, is necessary, especially in the area of early detection of breast cancer. Yet, in its extensive review of the literature, the Subcommittee found little evidence of a Federal education effort in this area, or in the general topic of breast cancer.

A nationwide campaign should be waged to encourage monthly breast self-examination by all women 20 and older, and to convey the news that mammography, administered judiciously, is safe and a valuable diagnostic tool. Just as the introduction of the pap smear has meant a decline in the death rate from uterine cancer by more than 70%, an all-out campaign to inform women about developments in breast cancer detection could dramatically reduce the number of breast cancer deaths.

— A nationwide network of community-based cancer detection centers -- based on the cost-effective principals employed by leading cancer researchers like Dr. Philip Strax at New York's Guttman Institute — is suggested. This network could be set up in connection with NCI's 20 Comprehensive Cancer Centers and would begin to offer to women at low or no cost the breast cancer screening that could save their lives.

— The Breast Cancer Detection Demonstration Project, a large-scale screening project begun by NCI and ACS in 1973, was designed to demonstrate to the medical profession and the public at large the feasibility of screening large numbers of women for the early detection of breast cancer. Over 280,000 women were recruited and examined using mammography and physician examination at 29 BCDDP centers for five consecutive years, and five more years of follow-up. The BCDDP ended its screening phase in 1981, and 3,557 cases of breast cancer were detected. More than 80% of all new cancers among the women were found at the detection centers. The study is an important one as far as it goes, but no long-term survival statistics have been published. We would encourage that the longitudinal study continue, in order to provide additional data on the merit of early breast cancer detection.

— Continued active research to identify the specific cause or causes of breast cancer is still a top priority. However, we have learned a lot about the ways of detecting breast cancer, and about the importance of early detection. Until a cure is found, early detection remains the most promising way of reducing mortality rates.

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DO YOU HAVE ANY LOW COST CLINICS WHICH OFFER SCREENING, MAMMOGRAPHIES, AND/OR SELF EXAMINATION INSTRUCTION WHICH SERVE THE RESIDENTS OF YOUR STATE AND WHICH YOU WOULD REFER TO THOSE INTERESTED? *

STATE	YES **	NO	NO RESPONSE
Alabama		X	
Alaska	X		
Arizona		X	
Arkansas		X	
California		X	
Colorado		X	
Connecticut	X		
Delaware		X	
Florida	X		
Georgia	X		
Hawaii		X	
Idaho		X	
Illinois			X
Indiana		X	
Iowa	X		
Kansas		X	
Kentucky		X	
Louisiana	X		
Maine		X	
Maryland		X	
Massachusetts	X		
Michigan	X		
Minnesota	X		
Mississippi	X		
Missouri	X		
Montana		X	
Nebraska		X	
Nevada		X	
New Hampshire		X	
New Jersey			X
New Mexico	X		
New York	X		
North Carolina			X
North Dakota		X	
Ohio	X		
Oklahoma	X		
Oregon	X		
Pennsylvania	X		
Rhode Island		X	
South Carolina		X	
South Dakota	X		
Tennessee		X	
Texas		X	
Utah		X	
Vermont		X	
Virginia		X	
Washington		X	
West Virginia		X	
Wisconsin		X	
Wyoming		X	
District of Columbia	X		
TOTAL	20	28	3

* Responses provided by state departments of health

** Includes states which offer only low cost physician check-ups. The Subcommittee estimates that no more than 10 states have available low cost mammographies to women at risk of breast cancer.

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STATE	YES **	NO	NO RESPONSE
Alabama	X		
Alaska	X		
Arizona		X	
Arkansas	X		
California	X		
Colorado		X	
Connecticut		X	
Delaware	X		
Florida		X	
Georgia	X		
Hawaii	X		
Idaho		X	
Illinois	X		
Indiana		X	
Iowa	X		
Kansas		X	
Kentucky	X		
Louisiana	X		
Maine	X		
Maryland	X		
Massachusetts		X	
Michigan		X	
Minnesota	X		
Mississippi		X	
Missouri		X	
Montana		X	
Nebraska	X		
Nevada		X	
New Hampshire		X	
New Jersey	X		
New Mexico	X		
New York			X
North Carolina	X		
North Dakota		X	
Ohio		X	
Oklahoma	X		
Oregon	X		
Pennsylvania	X		
Rhode Island	X		
South Carolina		X	
South Dakota		X	
Tennessee		X	
Texas		X	
Utah	X		
Vermont		X	
Virginia	X		
Washington			X
West Virginia	X		
Wisconsin	X		
Wyoming		X	
District of Columbia	X		
TOTAL	27	22	2

* Responses provided by state chapters of the American Cancer Society

** Includes states which offer only low cost physician check-ups. The Subcommittee estimates that no more than 10 states have available low cost mammographies to women at risk of breast cancer.

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Ms. OAKAR. I would also like to submit for the hearing record the prepared statement by Ms. Ann Jillian, who is a well-known actress and former breast cancer patient. She wanted to be with us today.

[The prepared statement of Ms. Jillian follows:]

September 15, 1985.

U.S. HOUSE OF REPRESENTATIVES,
Select Committee on Aging, Subcommittee on Aging, Washington, DC.

DEAR CHAIRMAN PEPPER, MS. OAKAR, AND ALL SUBCOMMITTEE MEMBERS:

Thank you for inviting me to testify both in person and by mail. My schedule does not permit me to attend in person, but please file my letter at this time.

I am a victim of breast cancer. On April 12, 1985, both my breasts had to be removed to save my life. Due to my visibility as an actress, I received over forty thousand pieces of mail when the media reported my surgery. Approximately half of these cards and letters came from other victims of breast cancer. I read all the mail from victims and have had contact with some of them either by phone or by mail. Although each case of breast cancer is unique, I have noticed certain similarities among many of the victims who have written me and also in my own case. They are:

(1) Early detection means continued life for the breast cancer victim.

(2) There appears to be a general consensus among victims that we lacked crucial information before cancer was detected.

(3) Some women are not going to the biopsy stage of detection as soon as they should. Precious time is being wasted before a certainty regarding the presence of cancer is known. It appears to be the frightened, uninformed victim who is the cause of this unnecessary delay, although it seems that doctors in some cases tell the victim to simply "watch" the condition for a period of time, instead of strongly advising a biopsy, which would allow for a certain diagnosis. A biopsy is a small price to pay for knowledge that could save one's life.

(4) I believe females are learning about self-examination too late in life. Some medical experts have stated that both self-examination and medical examination should occur at about age 35. I must disagree. As soon as girls develop breasts, they should be taught how to perform self-examination. If this age is premature, at least the girl will be prepared for self-examination when the "correct" age rolls around.

I must also disagree with the notion that women should get a "base-line" mammogram (the first mammogram to which future mammograms will be compared) at age 35. My knowledge indicates that women should start receiving mammograms at a much earlier age. I have received many letters from ladies who have stated that they were in their twenties when they underwent mastectomies. I can only hope that these ladies are the exception to the rule. If they are, perhaps the statistics should contain a written message that the numbers do not take into consideration "exceptions" such as the ladies who have discovered breast cancer in their twenties.

I would like to relate another reason for my concern for age limits. While waiting for a prosthesis fitting, I noticed a teen-age girl reading her school books. I thought she was waiting for her mother, but an attendant called her into the office. After asking one in authority, I was told that she too was a breast cancer victim. I was shocked! What are the numbers of high school girls who have had breast cancer? It cannot hurt to make the public aware that it can strike women in their teens and twenties as well as those 35 and older. I request that word be sent out to reflect this.

(5) I have always questioned statistics, whether they are complicated medical numbers or simple Nielsen ratings—something that concerns me as an actress on television. These numbers can be manipulated to reveal just about anything that the researcher wants them to reveal. The public must know that cancer does not discriminate. It can strike anyone at any age.

RECOMMENDATIONS

Perhaps we might begin by tossing out the statistics book and alerting the public that cancer of the breast can happen during one's life at just about any age. Although it might occur more often at a later age, we should never walk around with a false sense of security. We must be prepared for the exception to the rule.

It might be wise to take "practice breasts" that are at most breast centers to high schools and teach both girls and boys about self-examination. Most boys will marry and should be aware of self-examination. By becoming familiar with their breasts at an early age, girls will not fear self-examination as they enter "higher risk" groups.

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I am sure that the knowledge gained would be worth the few giggles of the adolescents.

Television is the quickest, most efficient means of informing the public. Its power has been demonstrated to me throughout my career. Why, then, is national television not being used to disseminate crucial information on breast cancer to the public? I have offered myself, free of any fee, to perform Public Service Announcements for the American Cancer Society. I am aware that because of my high visibility and bout with cancer I am in perhaps the best position of any female to "spread the word" via national television. However, I have not been called upon to make these announcements. I attend American Cancer Society banquets in honor of those who have furthered cancer research, but I could be used more effectively in the medium in which I work. Since I was on the cover of People magazine, I have been made aware of at least one case where my story saved a life that was otherwise going to leave us. I want to do more. I hope this subcommittee will relate this to those in decision-making positions at the American Cancer Society.

It is too late to save my breasts, but it is not too late to save those of other ladies. I pray for the day when all cancer will have a cure. I pray that not another lady will have to go through what I and so many other ladies have experienced. I pray for those who have died of this, and for those dying at an alarming rate because they did not detect cancer early enough or because they lacked information. I pray and cry for every little girl I see as she giggles as only a little girl can. I see myself in that innocent child, unaware of what was going to happen to me one day, and I pray it will not have to happen to all those other little girls.

I wish to commend this committee on your interest in breast cancer and your willingness to try to make a difference for all of us. I thank God for your interest, and I pray that God will give your investigation that power to make changes where you find ignorance—replace fear with confidence—permit life where there once was death—replace discrimination with love in both the home and the workplace—and, above all, I pray that all will be done to seek out the cure for every life-taking disease.

Thank you, and God bless.

Sincerely,

ANN JILLIAN.

Ms. OAKAR. I am especially pleased to be able to welcome our first witness, Mrs. Susan Ford Vance, who is the chairwoman of the National Breast Cancer Awareness Week. There are a couple of reasons why we are especially happy to have you here, Susan. One is because of the fabulous work you are doing in your own right to make people more aware of what this disease is all about and how they can cure it. You in your own right as the mother of two daughters, I understand, are to be congratulated.

We are also happy to have you here because your mother is one of the heroines of American women. Betty Ford is to me one of the most outstanding women in the country for a number of reasons, not the least of which was her lack of fear in exposing her own problems with the disease of breast cancer. I believe the manner in which she did it saved millions, or thousands of lives at least, across the country. She continues to work in that direction and other directions to say it's OK if you get this disease. There are things you can do about it. Don't be afraid of it. And do the things that you have to do.

Susan, I just want to say on behalf of the whole committee and Senator Pepper how very excited we are to have you here today. We would like to have your statement in any way that is most comfortable for you.

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PANEL ONE—THE PROBLEM: SUSAN FORD VANCE, CHAIRPERSON, NATIONAL BREAST CANCER AWARENESS PROGRAM

STATEMENT OF SUSAN FORD VANCE

Mrs. VANCE. Thank you.

As a child, I used to take a great deal of pride in watching my father work in these rooms.

I am Susan Ford Vance, and I am honored to be here today to testify on behalf of the importance of public education about early breast cancer detection. Breast cancer is a leading killer of women today. In fact, 1 in every 11 women will get breast cancer this year, almost double the rate 20 years ago. Yet, breast cancer is one of the easiest cancers to treat if detected in the earliest stages.

The problem with early breast cancer detection is twofold.

Many women do not know about early breast cancer detection methods such as breast self-examination, regular physician examination, and especially mammography, an early detection technique that can detect breast cancer up to 2 years before it can be felt by hand.

The second issue is one of cost. Mammography is an expensive procedure that many women simply cannot afford. This makes it a privilege only for those who can afford it. If made available to women nationwide, mammography will save the lives of thousands of American women. Mammography is the best weapon women have in this deadly battle.

In 1986, 1 in 11 women will develop breast cancer. I keep repeating the statistic 1 in 11 women in my mind over and over again. Statistics, victims and families of victims will tell you, are meaningless when the disease affects their lives. Of that 1 in 11 women, I wonder what the statistics really are when those who are indirectly affected by breast cancer are tallied. The cost in pain and suffering for the family is just as great for the victim. I know, I have been there. And I have been scared, and I will never stop being scared.

I spoke before of being able to afford the privilege of mammography. I chose that word carefully, for millions of American women the prohibitive cost of one mammography makes it just a privilege when it should be a right. Even worse, many women do not even know what a mammogram is or how it can help. There is a great need for public education about early breast cancer detection.

Right now, mammography is as critical in saving the lives of women from breast cancer as the pap smear was to saving women from cervical cancer years ago. Through public education, women now are aware of the importance of pap smears in detecting cervical cancer. Now, with your help, we must make women aware of mammography in detecting breast cancer at a stage when the disease is still localized and readily treatable. Therein lies the greatest chance for survival.

Let me tell you about my own experience with breast cancer. First, as a woman with a family history of the disease, I am at high risk. I am frightened that it will happen to me, or someday to my daughters.

I remember the morning when my mother went into the hospital to have a biopsy. The White House physician had just found a

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lump in her breast. A few hours later, she emerged from the operating room after having a mastectomy. I was 17 years old, and I was terrified. There was my mother, not just 1 woman in 11, but my mother. How would she recover? How would she survive? What kind of drugs or radiation would follow? Could I help her? Could I face it? Could I live with it? How would we have to go on without her? Could we?

After surgery, we were allowed to see her briefly. I remember my dad and my three brothers were standing with me. There she was, lying there white as a bed sheet. Tubes were attached everywhere, machines were running, and her bandages were filled with blood. I remember thinking, Mom was such an active woman. Would she ever be able to get back on her feet? How would this affect her marriage to my father?

Most people weren't aware of how truly courageous my mother was, of the courage it took my mother to perform even the smallest task. Because so much tissue and muscle were removed, mother could barely move her arm. She waved to the press as she and dad left the hospital. If only they knew how much pain she was in, what it took for her to raise her arm and wave. It seemed to me that people took so much for granted in life.

Then came the slow recovery. I had to go back to school. I was afraid that, when I returned for a visit, mom wouldn't be there. One day I came home and went into her room. She was undressing. At first I couldn't bring myself to look at her, but something made me look. Then I had a flashback to my childhood. I used to stop and stare at people who were missing a limb and say, "Mommy, look at that person." Now I was staring at my own mother. I couldn't bring myself to say anything. I couldn't believe it. I just stood there and stared.

I often wonder if my mom remembers that day. I will never forget it.

It seemed as if my whole life had changed. While mom recovered, I remember being with my dad at White House parties and trying to behave like a First Lady. There was really no one to talk to about mom's cancer. I didn't want to keep bringing it up in front of dad and my brothers. They too were suffering, right along with my mother. If often seemed that there was nowhere to turn.

Thank God that she was one of those lucky ones. It has been over 10 years, and the disease has not recurred. But 10 years later, I find myself still fighting the battle against breast cancer.

Twenty years ago, the number of breast cancer patients was 1 in 20. Ten years ago, it was 1 in 15. Today it is 1 in 11, and moving toward 1 in 10. The incidence of breast cancer has risen significantly over the past two decades. It's time to do something about it now.

As chairperson of the National Breast Cancer Awareness Week, a program to encourage early breast cancer detection, I am working to bring this issue to the public front, to urge women to do all they can through early detection, not only to save their breasts but their lives. Breast cancer isn't like lung cancer, where in most cases a woman chooses to be at risk. With breast cancer there are no choices but early detection.

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The National Cancer Foundation, with funding from Stuart Pharmaceuticals, is sponsoring the National Breast Cancer Awareness Program to bring this issue out into the open. But we can't do it alone. Now it's time for Congress to consider a means for making early detection available and accessible to all women. The private sector must join forces with government in affording everyone the opportunity to the right to early breast cancer detection.

Thank you.

Ms. OAKAR. Thank you very much, Susan, for being so personal in your testimony and for the work that you do.

Let me ask you this. Do you feel the Federal and State and local governments have a responsibility to call attention to the issue of breast cancer? It's almost as if there is an apathy toward it today. Yet, as you mention in your statistics, and I gave a few myself, it is still devastating and has been on the increase, not the decrease. What role do you think the Federal Government, for example, should play in making people aware?

Mrs. VANCE. I think your legislation is very accurate in the sense that it will bring the cost down. As we discuss the price, it is a privilege to get a mammogram now.

We have the YWCA's this week working with us, having workshops all over the States, to encourage women to do proper self-examination and teach them when to go and get a mammogram and to see a doctor on a regular basis.

Ms. OAKAR. Do you think that the private sector can also play a role? Your foundation is sponsored by a pharmaceutical company, for example. Is there a role that the private sector can play as well in making people aware of the problem and also aware of prevention?

Mrs. VANCE. I think probably everybody can take part in the whole program in the sense that I think husbands can encourage wives to do self-examination on a monthly basis. I think insurance companies can cover at least partially the cost of a mammogram. There are hundreds of things we can do. I think we can only start touching on them now.

Ms. OAKAR. I feel as if I have known you for a long time. We just met a few minutes ago earlier today. I think all of us remember when you were a teenager at the White House. You reminded me that your father was here at the House, so you remember his swearing in. This is old home week for you, in a sense. And now you have two little girls. How old are your little girls?

Mrs. VANCE. Two and a half and five.

Ms. OAKAR. What kind of instruction or information will you tell them when they are old enough about this disease?

Mrs. VANCE. I would, hopefully, like to think that maybe there will be a vaccine by the time they are 18 or 19, when they will start practicing proper self-examination. But I will make them aware and educate them, as I have been educated. I feel like it's only the people who have been touched by the disease are the ones that are participating and encouraging young girls to learn about it. So, I think probably just educating them is the best I can do unless there is a vaccine at that point.

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Ms. OAKAR. After this Breast Cancer Awareness Week, which occurs, I guess, once a year, what else will your group be doing? Do you have any other programs in mind around the country?

Mrs. VANCE. We don't right at this point. We are going to wait and see how the numbers come in. We do have a free brochure that we are offering to people who write the National Cancer Foundation that will answer the basic questions about breast cancer and women. If we can just save one life and one breast, then we have served our whole purpose for the year.

Ms. OAKAR. I think so, too. I want to thank you for being here and congratulate you on the great work you are doing. Please keep it up. Extend to your mother and father our best regards. Tell your mother just keep plugging. We just think she's fabulous. We miss her.

Mrs. VANCE. Thank you.

Ms. OAKAR. Thank you very much.

We are very, very pleased to have patients and relatives of breast cancer patients who have come here today. We would like to have the form of a panel.

Mrs. Nancy Brinker is the founder and chairperson of the Susan G. Komen Foundation, which is an organization named after her sister who had breast cancer. It is a private organization that is helping to fund research in this area. We need more research in the area to cure this disease.

We would like to hear from you. If you can limit your testimony, then we will have a little more time for questions. Marie, thank you very much for being here. We are happy to have you here.

Before we begin, I see Senator Pepper here. He is in the background there saying hello. So, maybe my chairman would like to greet you as well before we start your testimony.

I don't often encourage people to applaud chairmen, but I am going to ask the audience to give a little round of applause to my chairman. He is terrific.

Susan, why don't you come back? Maybe the Senator would like to greet you as well and the other witnesses.

Senator Pepper is chairman of the Rules Committee. We have something called Gramm-Rudman brewing. It's really important that he be at other meetings at the time we started. Let me ask Senator Pepper if I would turn the chair over to him.

STATEMENT OF CHAIRMAN CLAUDE PEPPER

Mr. PEPPER. I will only share it with you, if I may.

I apologize for being late. I had an engagement downtown. Then I had to run over and vote on that unhappy thing we have where you have to confirm the journal of the House.

I am delighted to be here this morning and to share this occasion with Ms. Oakar, one of the great leaders in the cause of right for people who have the dreaded disease cancer, who are threatened with premature death. My remembrance of the effort to do something about this monster cancer goes back to 1937, when I was a Member of the Senate. There was a crippled Senator from the State of Washington named Homer Bones. He came around to all of the Senators with a bill asking us to sign on with him. He said,

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let's set up a National Cancer Institute. The bill provided $500,000 a year for the support of this institute.

The House passed it, and the bill took effect after approval by the President. Several years went ahead; $500,000 a year was the amount of funds contributed by the Government to the National Cancer Institute.

Finally a great angel—and, Mary Rose, I hope we can find some kind of an award that the Congress might bestow which would be fitting for this great and remarkable lady—Ms. Mary Lasker from New York. She came to me. She said she and her husband, Albert Lasker, who was supposed to be the man who pioneered modern advertising in America, had conferred, and they decided: let's see if we can't get the Government of the United States more heavily behind this. Let's introduce a bill to appropriate $100 million, to remain available until spent, so there would be some continuity in meaningful research in cancer.

I introduced a bill and set up a subcommittee to hold hearings on it. Former Senator Nealy, who was then a Member of the House, introduced a companion bill in the House. He had hearings on that.

Later in the year, the word came to me from Senator Taft, who, as you know was a great American, but on the conservative side. He said he would support a bill to appropriate $75 million, to remain available until spent. So then those of us who were in favor of providing more help to fight the monster cancer got together and passed the first bill appropriating a sizable amount of money, as I recall, some $8 or $9 million. The next year it went up to $14 million, and since that time, it has gone on up and up until now it's about $1.1 billion, or something like that.

We have been considering lately, we have had some conferences with Representative Natcher, chairman of the House Appropriations Committee on Health, and Representative Henry Waxman, who is chairman of the Commerce Committee on Health and the Environment, about the possibility of starting another Manhattan project for cancer. We would just tell the people who are trying to find the cause and cure for cancer: listen, don't ask us how much money we are going to appropriate for you; you tell us how much money you can wisely spend. Just like the people that were developing the atom bomb, all they needed to do was to tell the War Department that they needed some more money, and they got it, because they were engaged in something the Government wanted to see accomplished.

I can't believe that we will go on with what we are doing now, and allow over 400,000 people a year to be the victims of this monster cancer. One of its victims was my lovely dear wife, who passed away with cancer 6 years ago. So now we are talking about another aspect of it, the breast cancer.

Incidentally, Mary Rose, the other day I called Dr. Rauscher, who used to be head of the National Cancer Institute, who has been down to see me about this Manhattan project idea. He told me that this new drug that came from Sweden, that we had such hope for at one time, interferon, he told me that he thought interferon was having some efficacy against breast cancer. I don't know.

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I won't take the time of my colleague here, distinguished and beloved colleague that she is. I won't take the time to read my statement. I have got a statement here that puts together a lot of information the staff has accumulated.

[The prepared statement of Chairman Pepper follows:]

PREPARED STATEMENT OF CHAIRMAN CLAUDE PEPPER

Members of the Subcommittees. Ladies and Gentlemen. Cancer is of tremendous concern to the people of the United States and to people worldwide, and rightfully so. We have no cure—no solution—for this deadly and frightening disease.

Cancer is devastating to the elderly people of this country. Persons over 54 years of age constitute 81 percent of all cancer deaths, and over 400,000 people in America die every year from cancer. People over the age of 65 account for 60 percent of all cancer deaths.

The subject of today's hearing, breast cancer, is of particular concern to our elderly women—for about 39,000 women will die of breast cancer in 1985 and about one-quarter will be over the age of 75. Breast cancer is an epidemic in the United States—1 out of 11 women will get it. And over 1,500,000 women have or have had breast cancer in the United States today. About 120,000 new cases will be diagnosed this year alone. Practically every family has, unfortunately, been affected by this disease which is one of the most serious health problems that we have among women in this country. I might add that breast cancer affects not only the woman, but also their husbands, children and loved ones.

Last year, this Subcommittee convened a hearing on the progress in breast cancer research. We found that if breast cancer were detected earlier, we could reduce deaths from breast cancer by 30-40%—saving 10,000 lives annually. We also found that if detected earlier, breast cancer need not be so radical—so devastating physically to a woman. Most important, I believe, was our finding that the combination of breast self-examination, regular physical exams, and mammography can be as effective in reducing breast cancer mortality as the pap smear has been in curbing deaths due to uterine cancer. Since the introduction of the pap smear, during the last 40 years the death rate from uterine cancer has declined more than 70%. There are striking similarities in survival rates between the success associated with pap smears and the potential for mammographies and breast self-exams in reducing breast cancer mortality today.

Knowing that breast cancer deaths can also be substantially reduced through earlier detection, it is unconscionable to learn that only 15-20% of all women "at risk" of getting breast cancer seek and obtain preventative screening for early detection and treatment of breast cancer, on an annual basis. Most women wait until symptoms express themselves and by then the prospects for survival or less radical surgery are substantially reduced.

Sadly, the Subcommittee found that the reasons so many women do not receive the benefit of detection or new preventative technology is directly related to the awareness, the affordability, and the availability of these new screening and detective procedures.

First, we found that most women are not aware of screening techniques available to them which if employed could substantially lower their risk of a devastating bout with breast cancer or minimize surgical intervention required to halt its progress. Testimony today will highlight the need to alert women to choices they have available to them to become a "partner" in preventing and treating breast cancer. The fear that "choices" are unavailable steers many women away from seeking routine screening for breast cancer.

Second, we found women can't afford most preventative measures currently available for earlier detection and treatment of breast cancer. Medicare will not pay for most preventative services, like early detection of breast or other cancers. Also, a 1984 Subcommittee survey found that the top 50 insurance companies in the United States do not reimburse women for breast cancer screening tests unless women are symptomatic or have a history of breast cancer in their family, and then it is often too late.

Interestingly, we will hear today how it is possible to conduct cost-effective breast cancer screening at less than one-quarter the cost of what Medicare and most insurance companies pay for similar tests.

Thirdly, we found that for those women who do want to take preventative measures—to get screened regularly and obtain less radical surgical intervention—availability of screening and detection centers—outside of a hospital setting requiring

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physician referral—is almost nonexistent. Those screening and detection centers in existence are often difficult to locate.

In an effort to determine what is available to the average concerned American woman, the Subcommittee attempted to ascertain the availability of inexpensive, high quality, mass screening and detection facilities available in the United States. We contacted every State chapter of the American Cancer Society and every Department of Public Health.

We found that:

Seventy-five percent of State American Cancer Society (ACS) chapters told a woman to contact her physician.

In cases where a woman did not have her own physician, one-third of the State chapters advised her to call her local medical society.

Many State ACS chapters (about 40%) were unaware of any low-cost, quality breast cancer screening facilities within their State. The remainder advised the Subcommittee of facilities offering services ranging from complete screenings to those that only taught breast self-examination.

The majority of State Health Departments knew little about State efforts in breast cancer detection. About 80% of the States referred the Subcommittee to the State chapter of the American Cancer Society for further information.

About 60% of the State Health Departments knew of absolutely nothing in the way of low-cost screening of any sort for breast cancer.

Next, we attempted to determine what the Federal government was doing in the area of breast cancer. We found that the National Cancer Institute is largely responsible for much of what we now know about the early detection and treatment of breast cancer today. Major research undertakings over the last 30 years by the NCI have resulted in this Subcommittee's awareness of the fact that if detected earlier, breast cancer surgery need not be so radical and survival rates can be substantially increased. Given these impressive and heartening findings of the National Cancer Institute (NCI), the Subcommittee was shocked to review the NCI's efforts to demonstrate the effectiveness of these findings. Essentially nothing is currently funded to demonstrate the effectiveness of early detection and screening. Of the 3,000 grants and contracts currently supported by the NCI, only 3 are related specifically to "improvements" in breast cancer screening. None provide for the dissemination of information on screening to the American public. I look forward to hearing why the National Cancer Institute is not doing more to increase the numbers of women getting mammographies and about what barriers exist in accomplishing this objective.

I have always believed that every dollar we have invested in the National Cancer Institute and its work has been well invested and I still do. I was surprised to learn that the NCI is one of the few of all the institutes within the NIH to have its budget cut—in real terms by $130 million, or 20 percent, over the last ten years. This must not persist.

The increases in cancer research—and in this instance—the application of cancer research, are inadequate for the important tasks ahead. I intend to introduce legislation, which I hope my colleagues will cosponser, to establish community-based cancer detection centers—based on the cost-effective principals employed by leading cancer researchers, like Dr. Philip Strax—whom we will hear from today—so that we might commence our campaign and commitment to the end of the unnecessary toll of breast cancer. The bill will mandate that the National Cancer Institute, through its 20 Comprehensive Cancer Centers around the country, begin to offer to women at low or no cost the breast cancer screening that could save their lives. We will hear today from experts around the nation as to the need for such centers.

We are fortunate to have with us today a host of distinguished witnesses, those whose lives have been personally touched by cancer, and expert researchers in the field. We thank you for coming.

Our first witness is Mrs. Susan Ford Vance. Mrs. Vance is the Honorable Chairperson of the Breast Cancer Awareness Week. She is a worthy spokesperson for this worthy issue. She is a woman at risk—the daughter of the former President of the United States and the former First Lady Betty Ford who herself was stricken with breast cancer and bravely spoke out about this fearful disease. She is the mother of two children—two darling girls—who are also at risk. I know we all will benefit from her choice to speak on behalf of those who are similarly situated. We look forward to your testimony. Thank you.

Mr. PEPPER. What we are trying to do is develop new techniques, new means, to success with respect to breast cancer. In our office, the senior lady in my office, Mrs. Liz Bedell, had an appearance of breast cancer. At first the doctor told her he thought it might be

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kept from being serious. Finally he thought it might be necessary to have an operation. She had an operation. She went down and down and down until after a year or two she passed away.

The senior man in my Miami office died with lung cancer. My wife died with cancer in the body. Everywhere around us people are falling to that monster.

This is one type of cancer we can concentrate on and where there is much more hope than there is in some kinds of cancer, of saving the lives of wonderful worthy people.

Susan Ford Vance, thank you very much for appearing here today. My staff tells me to give you a warm thanks, and I am sure it's deserved. We do appreciate it. I have heard about what you have been doing and the great help that you have been giving us. We are very grateful to you, and to all of you who are here today.

Mary Rose, why don't you just go ahead?

Ms. OAKAR. Thank you, Senator. We were about to hear—and thank you again, Susan, for being here. We are about to hear from Marie Nash. Marie, why don't you proceed?

PANEL TWO—BREAST CANCER PATIENTS AND THEIR RELATIVES: CONSISTING OF MARIE NASH, WASHINGTON, DC; JOE HENNESSEY, WASHINGTON, DC; MINERVA CHASKES, FORT LAUDERDALE, FL; AND NANCY BRINKER, FOUNDER AND CHAIRMAN OF THE BOARD, SUSAN G. KOMEN FOUNDATION

STATEMENT OF MARIE NASH

Ms. NASH. Thank you for having me come today.

I am Marie Nash. I am 49 years old and the divorced mother of two children, a 10-year-old boy and an 18-year-old girl for whom I am the sole source of financial support. I had a modified mastectomy and a lymph node dissection for breast cancer, in June of this year. Currently I am a registered nurse in an inpatient hospice. There is no history of cancer in my family.

I have had fibrocystic breast disease for over 20 years. About 23 years ago, I had a moderate-sized benign tumor removed. Because of the way the underlying tissue healed, it was always difficult to examine that breast. Over the years, I have had eight biopsies of both breasts, one when I was 7 months pregnant with my first child, another when my younger child was 4 months old and I was breastfeeding him. All of these biopsies were benign.

A woman's breast tissue changes with her menstrual cycle. That's why it is important for a woman to do her breast self-exam around the same time of her menstrual cycle each month, preferably the week after her period. She then gets used to what is normal for her and is able to detect abnormalities.

With the amount of fibrocystic breast disease I have had, it has always been difficult for me to know what is normal for me. The cysts are always present, and some are enlarging or decreasing at any time during my cycle.

Because of my marital and financial situation, there was a recent period of about 1½ years when I had no medical insurance. Now I have chosen the least expensive insurance available to me, which happens to be with a health maintenance organization, or an HMO.

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Soon after I was insured, I arranged for a complete physical with a nurse practitioner. Because of the fibrocystic disease that I have, she decided that I should be seen, and my case followed, by the female surgeon who does all the breast followups for the HMO. After examining me, the surgeon, advised that due to the extent of my fibrocystic disease, I should be examined by her monthly.

Under most insurance plans, that arrangement would have been financially impossible for me. I had a major advantage in that the HMO is a health maintenance organization and therefore, its focus is preventative medicine. It is of great interest to me that this group, which is vigorous in its attempts to control costs, would be the one to advise me so strongly to have monthly followups. No systematic checkups, except for breast self-exam, had ever been suggested by any of the fine physicians I had seen previously, and despite my medical training, it wouldn't have occurred to me to demand it from the HMO. My biopsies had always been negative; I am conscientious about my diet and my way of life; I have a positive attitude about life's ups and downs. So, I thought I might as well go along with the program. What could I lose?

I had a negative mammogram then in October 1983, and again in October 1984. I had monthly checkups from October 1983 through December 1984. Each visit included aspiration, which is a withdrawal by suction, of anywhere from two to seven cysts, involving both breasts.

Due to a number of family crises, I was unable to keep appointments from January through April 1985. My exam in May 1985 caused the doctor concern and she scheduled me for a biopsy the following week. This didn't alarm me because the area of concern was the same irregular area of the original tumor surgery 23 years ago. I was sure it would be scar tissue.

When the frozen section analysis resulted in a positive diagnosis for breast cancer, I was stunned beyond belief. As my surgeon held me and hugged me, I went through the whole litany of, "this can't be true. There must be some mistake," and so on. Denial and hope took hold of my life.

Friends came with me the next day for my talk with the surgeon. The lump was 2.5 centimeters—about the size of a quarter—and extended to the edges of the specimen, which meant it might be even larger. She recommended a modified mastectomy, a lymph node dissection, and immediate reconstruction. The next week was spent picking the brains of friends and colleagues to get information from the best medical resources I could find. I have an obvious advantage in that I am in the specialty of hospice/oncology nursing and have highly respected experts' opinions available to me. We discussed mastectomy versus lumpectomy with radiation, and many other aspects of the situation. After several second and third opinions from surgeons and plastic surgeons, I was sure about my decision to have the recommended procedure.

My daughter was graduating from high school, so I had the surgery early the following week. All went well, but the best part was my doctor's report to me when she received the pathology report that all the remaining breast tissue and all lymph nodes were negative. This was the answer to my fervent prayers through all of this. The doctor and I cried and rejoiced. Her comment was, "I am

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so happy for you. I wish this would be the report I could give every patient in this situation."

I am doing well. I have been back to work for several months. My daughter is doing well at college, and my son is very happy with his fifth grade teacher. I am having breast checkups on a monthly basis again. I had my annual mammogram last week, and it was negative. Through this entire time I have been supported continually by loving, concerned friends in my job and in my social and religious milieu. I am very conscious of a providential God caring for me in the midst of life's ups and downs.

I feel that I have been very fortunate, and that this experience has provided me time for reflection. As I sit here today, there is a message I would like to impart. Each of us must participate vigorously and educate ourselves thoroughly regarding decisions about our health care. We must also investigate and challenge the choices that are available to us in order to make the best personal decisions in an individual situation. We should support and encourage each other to take control and to assume responsibility for our own health care decisions.

With regard to early detection of breast cancer, one clear means of compassionate support and encouragement is the promotion of early detection by having mammography available in communities, with insurance companies funding the cost. The financial and emotional costs of breast cancer to a woman and her loved ones can be reduced significantly if detected early.

Thank you for this opportunity to be here today.

Ms. OAKAR. Thank you very much, Ms. Nash.

STATEMENT OF JOE HENNESSEY

Mr. HENNESSEY. My name is Joseph F. Hennessey. I live in Washington, DC. I am not a doctor. As a matter of fact, I am a lawyer. That is not an unusual occupation in Washington.

I claim no professional expertise in health care. I have been a husband. I am now a widower. I am the father of five children. As a concerned citizen, I hope it may be of some help for me to give some testimony which will ensure that our country as a caring Nation can take steps to develop awareness of the possibility and implications of serious illness.

My oral presentation will give special attention to breast cancer, although there are some experiential observations not confined to that which I will include in a written statement.

I am 53 years old. I was one of five children. My own mother died in 1934 of streptococcus. That is something that is unheard of since the day of penicillin. But this tragedy had great economic and emotional effects on my family. People never talked about disease in those days. Things were much different. Serious illness or death was never discussed, especially for children. Everything was shrouded in dread and mystery or avoided and buried.

Fortunately, our society has made great advances since then, but we have not come far enough. We do need to be better informed about serious illness and especially about breast cancer.

My wife Christina was 25 when we were married in 1960. Since about the age of 19 she had had a mass and thickness in her right

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breast. From the age of 19 and throughout her marriage, she had gone at regular intervals to her gynecologist/obstetrician. She was very dutiful about the Pap smear and other tests, including the monthly examination using manual means. Over many years, there appeared to be no perceptible change in the thickness which I described. Yet, she was uncertain and very hesitant about mammography. She decided that she would wait until she was 50 before she would have a mammogram. Unfortunately, that decision was overtaken by events.

In September 1983, my wife detected a lump under her right arm. She had a mammogram. The analysis indicated that, notwithstanding her faithfulness in taking other tests, she had advanced cancer of the breast. It had gone undetected for 2½ to 3 years. Apparently, as my wife had approached menopause, there had developed some kind of chemical change in that mass, and it had become loaded with cancer. The cancer had advanced dramatically. It was already well developed into her lymph system. My wife endured three surgical procedures: radiation, cobalt, chemotherapy, and other treatments too numerous to litanize here. None were successful. In early August of this year, she died at home and in the care of her family.

Fortunately, I as a lawyer could adjust to the demands of my law practice because of the support of my partners. I could care for my wife. The economic effects were substantial, but they could be absorbed. Also, through group insurance the problems of meeting medical expenses or personal care were not beyond reach, although treatment was very expensive. My wife received the best in medical care. She participated in decisionmaking. Her judgments were considered. The approach to her treatment and care was integrated and value oriented. None of the stereotypical horror stories about cancer obtained. None of her doctors were of the school that I sometimes pejoratively describe as the Woody Hayes school of medicine, where there were only winners and losers. Her care was very, very personal.

There is no way for me to describe the pain and devastation of those husbands and families for whom adequate medical care was not within reach. Yet, even for us, the emotional and psychological burdens were enormous. When we first learned of my wife's cancer, four of our five children were away at school. I knew how important it was to be honest with them, to let them know whatever I could, and to mediate the situation with all of its subtleties and nuances as faithfully as I could. Our children were encouraged to live out their own lives as best they could. They attempted to do so, with commendable courage and effectiveness. My wife's cancer did reach a stage at which they decided that they should all be at home to help her through to a peaceful death. And that is what has happened. She died at home peacefully and in the care of her husband and her children.

There were other difficulties which were not easy to accept. My wife's illness was painful. It progressed to her shoulders, her arms, her ribs, her pelvis, her spine, and finally to her liver. Her 50th birthday was spent at Sibley Hospital in Washington, where she had to have a pin inserted to replace a bone in her arm which had deteriorated to tissue because of cancer.

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My wife was an active woman. She had great religious faith. She knew that to put up with pain also meant to limit her activity. Therefore, she did not take heavy dosages of pain killers, sedatives, and other medication. I was tempted to intervene, to do something to ease the pain; but I did not do so. After all, as I explained to others, it was her disease, not ours. To take control of that disease was to take control of her, something that would have been contrary to our relationship. Yet, as her illness progressed and as her physical condition deteriorated, our family determined that the responsibility for treatment of the disease was no longer hers but ours. That was the point at which we took over decisionmaking and care which had as its chief purposes controlling and minimizing pain and ensuring a peaceful death at home, if possible.

Fortunately, our reach did not exceed our grasp. With expert guidance, we could medicate my wife until the end. In this we learned a lot about life and death and what is really important. We are closer as a family, but we still grieve, and we still have to make adjustments.

Everyone in our family has the unsettling feeling that with better understanding of, and earlier detection of, my wife's breast cancer through mammography, the effects of her disease would have been decidedly different. With the advice of a physician, our four daughters have already scheduled regular examinations, which are more comprehensive; and mammography is included as a part of that treatment. We urge that the committee and the health care industry and social organizations and other educational institutions do everything possible to ensure earlier detection of breast cancer by mammography. It will make a substantial difference to literally thousands of women, not to mention their husbands and their families and other loved ones.

Thank you.

[The prepared statement of Mr. Hennessy follows:]

PREPARED STATEMENT OF JOSEPH F. HENNESSEY, WASHINGTON, DC

THE NEED FOR IMPROVING STANDARDS OF MEDICAL CARE AT BETHESDA NAVAL MEDICAL HOSPITAL

In 1983, six weeks after my wife's first cancer surgery, her mother, the widow of an officer in the armed forces, underwent a major surgicial procedure for treatment of advanced lung cancer at Naval Medical Hospital in Bethesda. The surgeon for my mother-in-law has attracted considerable notoriety as a defendant in Court Martial proceedings in which he has been charged with five counts of manslaughter and 25 or so counts of misfeasance or malfeasance in the performance of professional duties. Several high level officials in the Naval Medical Center establishment have taken early retirement, have been reprimanded, or otherwise sanctioned in connection with an investigation conducted into the process of recruiting, evaluating and assigning this officer to very exacting and demanding surgical duties. Just recently there appeared newspaper accounts that additional Court Martial proceedings were initiated alleging that a Naval Officer perjured himself in material sworn testimony in the investigation of his role in this recruiting and evaluation process, if such it was.

According to several newspaper accounts, the surgeon who operated on my mother-in-law is legally blind and has been for several years. As a lawyer, I do realize that defendants in pending criminal proceedings are entitled to presumptions of innocence. Yet, considering the situation as a whole, and especially the issuance of so many sanctions which are related to the surgeon's recruitment and selection, and the outpouring of startling revelations about continued and unexplained incompe-

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tence and cover up, our family members have deep seated disquieting feelings about Naval Medical Center. The situation is not getting any better.

In the Spring of 1985, the lung cancer illness of my mother-in-law came out of remission and began to become more active. Perhaps this may have been triggered by the advance of my wife's illness, I don't know. However, and even more inexcusably, this development was not made known to the patient (my mother-in-law) for something in the order of three months, an unconscionable delay. Moreover, insofar as we can determine (and here the true facts are elusive), there have been at least two—and there may well be three—unrelated medical history cards at Naval Medical which have been kept separately for my mother-in-law.

It appears that one history card has her first name and last name, a second has her first name, middle initial, and last name, and a third may well have her first name, middle name, and last name, or something like that. In any event, for some time, perhaps years, perhaps longer, more than one medical history card was kept for my mother-in-law at Bethesda Naval Medical Center. Each card had incomplete information. Neither card referenced the other. It is inexcusable that any institution, let alone one supported by massive public funds, can or should be allowed by the Congress to operate in such a manner. Congressional oversight is absolutely imperative.

FOSTER BARTHOLOMEW URGENTLY NEEDS THE SUPPORT OF A CARING GOVERNMENT

In November of 1983, my late wife and I were seated in a reception room at Bethesda Naval Medical Hospital waiting to visit my late wife's mother when we were asked to read to a small boy who was in great shock and pain. That is how we got to know and learn about the tragedy of Foster Bartholomew.

Foster had lived and had grown up in Carriacou, a small island to the northwest of Grenada. In October of 1983, after our armed forces secured the island of Grenada, they proceeded to secure Carriacou as well. An armed forces vehicle traveled along one of the rural roads in Carriacou. As might be expected, this drew a crowd. A hand grenade rolled out of the truck. A fifteen year old boy picked up the hand grenade and pulled the pin. The pin did what it was designed to do; it detonated the hand grenade, killing the fifteen year old boy.

Foster Bartholomew, then age eight or nine, was standing near the fifteen year old boy who had pulled the hand grenade pin. When the grenade killed the boy, it maimed Foster. He lost an eye, he was wounded in the abdomen and spleen and, of course, he suffered severe emotional shock from which he has yet to recover. It was and remains a tragic situation.

Our uniformed armed forces made several unofficial but correct decisions to give Foster the best in medical care in the finest of humanitarian traditions of which this country has been justifiably proud. Foster was transported, successively, by helicopter, to a Med Vac station, to Roosevelt Roads in Puerto Rico, to Charleston, South Carolina, and, finally, to Bethesda Naval Medical Hospital where my wife and I first met him. Again, through unofficial but absolutely correct humanitarian decisions, Foster's mother, Ann Bartholomew, then employed as a domestic household worker in Venezuela, was brought by military transportation to be with Foster and an aunt who had already accompained Foster from Carriacou to Bethesda. Foster was treated surgically; he received other medical treatment and he was released from Bethesda Naval Medical Hospital a few weeks later.

My wife and I took an interest in trying to provide for Foster and his mother and aunt. We connected them with a support group at St. Augustine's Roman Catholic Church at 15th and V Streets, N.W., Washington, D.C. We have since contributed something in the order of a couple of thousand dollars for his medical care and maintenance.

For more than one year and one half now, I have spent literally hundreds of hours on a pro bono basis trying to see to it that a caring nation will help to provide for Foster's medical and education needs, since after all, though it was unintended, our armed forces were the instrument of the tremendous physical injuries and psychological disruptions to his person and his life. Pentagon personnel advised that I file, as Foster's next friend, a claim for compensation from an entity called the Army Claims Service. To proceed further, this group needs a medical evaluation for which the government is so far unwilling to pay, a classic Catch 22 situation if there ever was one. Also, there may be question about Foster's eligibility to receive benefits from the nation which maimed him because he is not a citizen.

More recently, Foster has had to undergo additional surgery at Kings County Hospital in Brooklyn, New York where Foster and his mother Ann Bartholomew now live. I had to advance the funds for this surgery, which was necessitated, I am

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told, from the rupturing of the wounds in his abdomen and from other internal injuries caused by the hand grenade. Foster, a growing boy, needs a new artificial eye. He needs psychiatric counseling. I have had contacts about Foster with the Offices of the Catholic Charities Service of the Brooklyn Archdiocese. Those people have been extraordinarily sympathetic, and responsive with limited resources but we cannot do it all alone.

Foster Bartholomew and his mother have been uprooted from their homes because of the violent acts of our government, however, unintended. They have been brought to our country and treated in the best humanitarian traditions of our armed forces and treated humanely in a manner of which those involved can justifiably be proud. Yet, it is impossible to sustain the attention of people in governmental positions and to involve them in trying to provide for the subsistence of Foster and his mother or for Foster's medical needs and his education. It is awkward for persons in an official position to do anything about Foster because he and his mother did not arrive in this country legally but rather through the unofficial and humanitarian routes described. Foster and his mother are ineligible for medical benefits because they are non-citizens and have established no legal right to be in this country. The only reason they are here is because our military people brought them here. And so we have another classic Catch 22 situation. If governmental officials try to make arrangements for Foster's medical and educational needs and his mother's subsistence, they can very well end up with having no choice but to initiate deportation proceedings.

Unless there is some break in this impasse, all of the generous humanitarian efforts of so many governmental officials will have gone for naught. Our country did, after all, bring about the maiming and injury of an innocent boy and the uprooting and displacing of this child and his mother. We can as a nation do better than abandon people just when they need us the most.

Perhaps a private bill giving citizenship to Foster and his mother may be the answer.

There is a real anomaly here. On the one hand, Foster Bartholomew and his mother have been injured and displaced, treated temporarily but then abandoned by a country which lacks the humanity and flexibility to respond to an urgent need for basic necessities of care, food and shelter which our armed forces created. Yet, according to recent accounts, Rupert Murdoch, for many years an Australian citizen, reluctantly decided to become an American citizen principally to meet statutory requirements of the Communications Act to make him eligible to own and control several major television stations which he purchased in acquisitions totalling literally billions of dollars. Mr. Murdoch has found Congressional sponsors who will whisk through his application to be a citizen. Foster has no Congressional patron. He will not receive adequate health care on Carriacou, and, as things now stand, he can't get it in the United States either, although he is most surely deserving of it under the circumstances.

Perhaps Foster and/or his mother should get some sort of administrative relief. Whatever is done it should be humane and it should happen immediately.

Thank you.

Ms. OAKAR. Thank you very much, Mr. Hennessey.

We are going to hold questions until after everyone has completed. It was very excellent testimony. Thank you.

Our next witness is Ms. Minerva Chaskes, from Fort Lauderdale, FL.

STATEMENT OF MINERVA CHASKES

Ms. CHASKES. I am Minerva Chaskes. I am a volunteer for Strax Breast Cancer Detection Institute. It is a nonprofit, low-cost fee of $35. A history is taken. A breast exam is given by a physician, a mammogram, and a report is made to her or to her doctor if she so desires. It is located at 5975 West Sunrise Boulevard in Fort Lauderdale, FL, on a main street with public transportation. It is accessible to the turnpike and expressways from all parts of the State.

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Patients do come from all parts of the State because of the low cost. I do not work directly with that phase, but most patients are covered by Medicare.

I became an involved member of the United Order of True Sisters, Margate, 64, the oldest nonsectarian philanthropic women's organization. Our main purpose is to work in cancer, and we adopted the Strax BCDI as our local project and became involved to help support financially as well as volunteering. Lodge 65 also participates in supporting same by volunteering.

I was routinely checked every year for the past 4 years. The last mammogram showed a very small mass that could not be detected by the examination of a doctor. I was given the choice of four surgeons. I immediately contacted one. I was told if the mass was malignant he would perform a lumpectomy, which means the small mass is removed, plus nodes under the arm, and checked for malignancy.

The operation was successful. I also had to take 25 radiation treatments. I am just fine. A check is kept on me by taking a mammogram every 6 months.

The institute is able to function because of our strong community support that our volunteers man. The institute tries to persuade patients to give donations. We send speakers to groups and health fairs to reach and educate as many people as possible on the importance of mammography.

Since our inception in Fort Lauderdale, we have screened over 18,000 women and saved 200 lives.

The bottom line is early detection saves lives, and screening is the key. I am living proof of that statement. You have probably heard of the book, "I'll Cry Tomorrow." I gave Dr. Strax a big hug and a kiss for saving my life and my dignity as a woman. And I don't have to cry.

I want to thank you people for inviting me and for the courtesies extended to me.

[The prepared statement of Ms. Chaskes follows:]

PREPARED STATEMENT OF MINERVA CHASKES, FORT LAUDERDALE, FL

Good morning. My name is Minerva Chaskes. I'm 72 years old and a volunteer for the Strax Breast Cancer Detection Institute. It is a non-profit, low-cost clinic located in Ft. Lauderdale, Florida, on a main street easily accesible by public transportation. Patients come from all over the state because of the low cost of services. I don't do my volunteer work in the billing office, but I think I can safely say most of the patients treated at Strax are covered by Medicare.

For a fee of $35.00, a medical history is taken, a breast exam is given by a physician, a mammogram is administered, and a report is made to her or to her doctor if she so desires.

I should tell you that I am an active member of the United Order True Sisters, the Margate, Florida Chapter. This is the oldest non-sectarian philanthropic women's organization in America. Our main purpose is to work against cancer, and we adopted the Strax Breast Cancer Detection Institute as our local project. We support the Institute not just with our money but, as I do by volunteering once a week, with our time. Now, a word about my personal story regarding breast cancer.

I was routinely checked every year for the past 4 years for breast cancer, and the last mammogram showed a very small mass that could not be detected by the examination of a doctor. I was given a choice of four surgeons, and I immediately contacted one of them. I was told that, if the mass proved to be malignant, he would perform a lumpectomy, which means that only the small cancerous mass is removed, plus the nodes under the arm. The operation was successful—there appeared to be no remaining malignant cells—but just to be safe, I had to take 25 radiation treat-

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ments. I am just fine. A check is kept on me by having a mammogram every 6 months.

The Institute is able to function because of our strong community support, both in terms of money and time. The Institute tries to persuade patients to give donations, but poor people are not turned away. We send speakers to various groups around the community and to health fairs, to reach and educate as many people as possible about the importance of mammography.

The bottom line is early detection saves lives and screening is the key. I am living proof of that statement.

You have probably heard of the book, "I'll Cry Tomorrow." If I hadn't been diagnosed early, I probably would be crying. Instead, I was happy, not to have had cancer, but to have been able to triumph over it. I gave Dr. Strax a big hug and kiss for saving my life and my dignity as a woman, and I don't have to cry.

Ms. OAKAR. Thank you very much, Minerva. That was terrific testimony.

Our last witness in this panel is Mrs. Nancy Brinker, who is the founder and chairperson of the Susan G. Komen Foundation. Maybe you can tell us a little bit about that as well. Thank you, Nancy, for coming all the way from Dallas, TX, although we know you're really from Peoria, IL.

STATEMENT OF NANCY BRINKER

Mrs. BRINKER. I thank you very much for inviting me, Mary Rose, and I want to thank you, Senator Pepper, and all of you here today who are here for this very, very crucial issue that we are talking about.

I am Nancy Brinker. A year and a half ago I awakened in the middle of the night and felt a lump in my breast. It is difficult to describe the sheer terror that one feels and that I felt that night. I felt it particularly because my sister had died of breast cancer 4 years before, when she was only 36. I had been through all of the chemotherapy with her, three courses of chemotherapy, nine surgeries, and waited endlessly in hospitals with her. Yet, I never thought it would happen to me. Only because of my experience with my sister did I honestly know what to do and where to go, should it happen to me.

I was very lucky. I was in a study group at a major cancer center at M.D. Anderson in Houston. I am convinced that, because I was in that study group, I knew to ask for and demand very aggressive treatment.

In 1981 I had founded the Susan G. Komen Foundation for breast cancer research as a part of a personal reaction of outrage against my sister's death and a way to carry out her wishes. She had been very active in the Cancer Society. And then my breast cancer only reinforced my determination to do something and to take action against this devastating disease. I am sure you can imagine that, as a young woman, it was not only frightening to me but devastating that in 10 years very little has happened, frankly, very little has ever happened to reduce the rate of recurrence and the rate of death from this disease.

I didn't want other women to suffer as Susan had, and I didn't want people to feel as helpless and frightened as I had. We are taking action. The Susan G. Komen Foundation has raised almost $2 million to date from private funds for distribution to public breast cancer research and screening projects. It is now much more than my own personal fight, because today I am here speaking for

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thousands of women. We have almost 1,000 women in our group in Dallas and in other communities around the country, who are working to form a national network to fight back. Our first job, though, is to educate.

Through a lack of education, both her doctor's and her own, my sister's breast cancer was not caught early enough nor treated effectively enough to give her a chance. For the 115,000 women and some men who will get breast cancer in our country this year, life or death depends on how early the cancer is detected and how effectively it is treated.

You have an opportunity, we have an opportunity here and, I believe, an obligation to make that life or death difference for hundreds of thousands of people. Women don't know enough about this disease. If they do know the warning signs, they often don't know where to go for medical treatment. As you have heard today, it is very expensive. As Susan Ford put it very, very aptly, it is a privilege to have a mammogram.

Low-income women can't afford a mammogram screening oftentimes. With the extensive awareness that we have created in Dallas, I still get calls in the middle of the night from women asking where to go, what should they do: I have a lump in my breast, but the insurance won't cover my mammogram. My Medicare doesn't cover my mammogram. Should I have one? Yes, of course. And then the foundation pays for it.

My sister didn't have this opportunity. She was a wife, a mother of two young children, a fashion model, a productive citizen who at the age of 32 discovered the lump in her breast. Her doctor removed it, and outrageously told her she was cured. She wasn't given a mammogram, not even after a malignant lump was removed, not even after it was proven that she was in a high-risk category at her age. Her alternatives were never explained. She was never given the chance that I later had, of choosing a more aggressive therapy.

After 6 months of her doctor telling her she was cured, the cancer spread to her lung. By the time we got her to a major cancer center, as you can imagine, it was too late.

When you are faced with a terrifying disease, you tend to believe what you want to hear. When the doctor told her she was cured, she wanted to believe that. Had there been laws requiring doctors to give their patients a thorough explanation of breast cancer and all the alternative methods, minimum treatments as well as maximum treatments, I believe it would have made a difference.

The Susan G. Komen Foundation is now helping explore those choices. We have funded projects at the University of Texas Health Science Center in Dallas and the M.D. Anderson Cancer Center in Houston. We set up two breast screening centers in Dallas. One grant from our foundation helped establish the Komen Breast Center at Baylor University Medical Center, which offers mammography and ultrasound examination. The center has a nonthreatening environment where women get results quickly, usually within an hour and a half, instead of waiting sleepless nights and being shuttled from one doctor's office to another, which often happens. The results are immediate.

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The figures that we have taken, the data that we have collected from our year of operating this center are also noteworthy. Think about this for a minute. This year we have screened 8,700 women. We detected 160 cancers. Almost 40 percent of them were nonpalpable, which meant they were treatable in a very early stage, which meant we have basically cured this many women. It gives them an excellent chance for a long recovery. Seventy-five percent of the cancers had not spread to the lymph nodes. Now, that is in sharp contrast to the results of most mammograms. Most are performed only after symptoms of breast cancer; it has been growing in the woman's body, basically, for 2 to 5 years, and the chances that it has spread are much greater. The treatment is therefore much more severe and more expensive. Our screening project clearly shows screening saves trauma and costs. Most importantly, without it, many of these women would not be alive today.

We also provide educational seminars. We raise funds. We are starting a mobile breast van in the area. We have just given a grant to Parkland, our county hospital, to establish a breast center there. Many of the patients at Parkland are covered by Medicare, but, as you know, Medicare does not currently cover the cost of mammograms.

Now that mammography is safe and involves only low doses of radiation, there is no excuse not to screen women. The statistics are overwhelming that the risk is far greater if you don't have a mammogram. We can alert the women to have one. We can educate. We can talk all day long. But the truth of the matter is, we have to make a way for the mammography to be less expensive. We need to have Medicare benefits to cover it. And insurance companies need to cover it under their plans.

Private foundations can raise money to establish breast centers. We can provide endowments, but we cannot do it alone. Ongoing preventive medicine has to be a partnership between Medicare, insurance companies, and private sources. We will not only save lives this way, but we will also save long-term medical costs.

Doctors at Parkland, our county hospital where we are doing this project, believe more than half of the cost of the screening will be returned in direct savings, because screening will detect cancer at these early stages. Currently, two-thirds of the breast cancers diagnosed in women have already spread to the lymph nodes, which requires expensive postoperative chemotherapy. Screening will save millions in lower chemotherapy costs, fewer terminal care costs, and added productivity to society from women who would have died.

Some attached testimony in my written statement will indicate a study in which 10,000 women screened at a cost of $50 a mammogram would create savings of up to $2.8 million. And that doesn't begin to count the value of the single life.

Also, with more extensive use of screening, I believe the cost of a mammogram will drop, much as the cost of a Pap smear did. When the Pap smear was introduced in the 1940's, it was expensive, and few doctors knew how to use it. It is now inexpensive, widely used, and routine. Since introduction of the Pap smear, the death rate from uterine cancer has dropped more than 70 percent. There are

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striking similarities, I believe, between that test 30 years ago and the state of mammography today.

I urge you to make mammogram screening tests available to women. Also, I urge you to allow women to participate in decisions about their treatment.

I don't believe I would have had the treatment or I would be here today, I want to emphasize, had I not had the alternative. I chose to have a mastectomy, and I chose to have chemotherapy. Sometimes those choices are not given to women.

The Susan G. Komen Foundation will continue to try to add to the knowledge about breast cancer by supporting our projects. We will continue to build screening centers and create endowments to do the things we can. But a private foundation in Dallas can't possibly reach the tremendous numbers of women whose lives will be cut short by this devastating disease. We need a partner, and your help is crucial.

The need for quality breast cancer screening throughout the United States is desperate. I implore you to take advantage of this opportunity to save so many lives.

Thank you very much, Mary Rose, for inviting me to be here today.

[The prepared statement of Mrs. Brinker follows:]

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PREPARED STATEMENT OF NANCY BRINKER, FOUNDER AND CHAIRMAN OF THE BOARD, SUSAN G. KOMEN FOUNDATION

Ladies and gentlemen: One in eleven of us, you, your wives, your daughters, your sisters, your mothers will get breast cancer at sometime during their lives.

There is no known way to prevent breast cancer, and there is no sure cure once you have it.

My name is Nancy Brinker. A year and a half ago, I awakened in the middle of the night and felt a lump in my breast. It is difficult to describe the sheer terror I felt. My sister had died of breast cancer four years before, when she was only 36 years old. I had been with her to chemotherapy treatments, I had waited in hospitals while she underwent surgery. Yet I never thought it would happen to me, and only because I had spent three years of my life watching my sister struggle to live did I know where to go and what type of treatment to demand. I chose to have a mastectomy and aggressive chemotherapy. But I am convinced that only because I went to a major cancer center, only because I knew enough to demand aggressive treatment, only because I was allowed to have a choice, am I here testifying today.

I had founded the Susan G. Komen Foundation two years before I discovered my cancer as part of a personal reaction of outrage against my sister's death. My breast cancer only reinforced my determination to do something--to take action against this devastating disease. I didn't want other women to suffer as Susan had, I didn't want other women to feel as helpless and frightened as I had. And we are taking action. The Susan G. Komen Foundation has raised almost $2 million in private funds for distribution to public breast cancer research and screening projects. The foundation today is much more than my own personal fight. Our first job [illegible] o educate.

Through a lack of ed[illegible] her doctor's and her own, my sister's breast car[illegible]ught early enough nor treated effectively enough [illegible] chance to live. For the 115,000 women and so[illegible] get breast cancer in our country this year, lif[illegible]nds on how early the cancer is detected and how effe[illegible] is treated. You have an opportunity, and I believe[illegible]ligation, to make that life or death difference for hundreds of thousands of people. Women do not know enough about this disease, and even if they do know the warning signs, they often have no where to go for medical treatment. Many women, particularly low income women, can't afford a mammogram screening test each year. Even with the extensive awareness the Komen Foundation has created in Dallas, I still get calls in the middle of the night from women who have no idea where to go or what to do. Many of them ask me, "I have a lump in my breast but my insurance won't cover this. Should I get a mammogram?" Of course, they not only should, but they must.

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My sister did not. Susan, a wife, mother of two young children, a fashion model, a productive citizen, active in her community, my best friend, discovered a lump in her breast at age 32. That lump was benign. The next one wasn't. Her doctor removed it and--outrageously--told her she was cured. Susan was not given a mammogram, not after the malignant lump was removed, not after the first benign lump was discovered. Her disease, breast cancer, was never discussed with her, her alternatives never explained. She was never given the chance that I later had, of choosing more aggressive treatment in an effort to prevent any recurrance of the disease. Six months after her doctor told her she was cured, the cancer spread to Susan's lung. By the time we got her to a major cancer center, it was too late. After nine surgeries, three courses of chemotherapy and radiation treatment, Susan died within three years. When you are faced with a terrifying disease, you tend to believe what you want to hear: when the doctor told Susan she was cured, she desperately wanted to believe that. Had there been laws requiring doctors to give their patients a thorough explanation of breast cancer and all alternative methods of treatment, it might have made a difference. At least, Susan might have sought a second opinion. I see no reason why any women in America today should be given false hopes instead of realistic choices.

The Susan G. Komen Foundation is helping explore those choices. The Foundation has financed research projects at the University of Texas Health Science Center at Dallas, the M.D. Anderson Cancer Center in Houston, Presbyterian Hospital's Radiation Oncology Center, and the Wadley Cancer Center. A grant from the Foundation helped establish the Komen Breast Center at Baylor University Medical Center in Dallas, which offers mammography and ultrasound examination to detect breast cancer. The center has a non-threatening environment where women can get results quickly, usually within an hour and a half, instead of waiting sleepless days and nights and being shuttled from one doctor's office to another. The way most breast cancer patients are terated: sent to different doctors, charged many repetitive fees, never fully informed, often means they fight two diseases: breast cancer, and fear of breast cancer. The Komen Center has screened 8717 women in the year since it opened, and that screening has detected 160 cancers. Of those, 38 percent were non-palpable, which gives women an excellent chance of being cured, and 75 percent of the cancers had not spread to the lymph nodes. That is in sharp contrast to the results of most mammograms. Most are performed only after symptoms of breast cancer, such as a lump, are discovered. By that time, the cancer has been growing in the woman's body for two to five years, and chances that it has spread to the lumph nodes are much greater. The treatment is therefore much more severe and more expensive. Our screening project clearly shows screening saves trauma and costs. And most importantly, without the screening, many of those women would not be alive today.

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The Komen Foundation also sponsors educational seminars, provides breast self-examination videotapes for all branches of the Dallas Public Library, and raises funds for a mobile breast cancer screening van operated by Baylor University Medical Center. We have just given a grant to Parkland Memorial Hospital, the public hospital in Dallas County, to establish a breast cancer screening clinic for its patients, many of whom are covered by Medicare. However, as you know, Medicare does not currently cover the costs of mammograms to screen for breast cancer.

Now that mammography is safe and involves only low doses of radiation, there is no excuse to fail to screen women. Statistics are overwhelming that the risk is far greater if you don't have a mammogram. With better education, I believe we will alert those women who can afford a mammogram that they can't afford not to have one. However, many poor women will still be unable to pay for this screening test. That's why providing Medicare coverage and insurance coverage for an annual screening mammogram is so essential. Private foundations can raise money to help establish these centers. We can provide endowments, but we can't do the loan. Ongoing preventive medicine must be a partnership between Medicare, the insurance companies and private sources such as ours. By recognizing that preventive care is just as, and often more, important than treatment after the fact, you will not only save lives, but also save long term health care costs.

Doctors at Parkland, our county hospital, where our Foundation is establishing a breast cancer screening project, believe more than half of the cost of the screening will be returned in direct savings because screening will detect cancer at early stages. Currently, two-thirds of the breast cancers diagnosed in women have already spread to the lymph nodes. That requires post operative chemotherapy. But with early diagnosis made possible by screening, more than three-fourths, 80 percent, of the cancers would not have spread to the lymph nodes and chemotherapy would not be required. Screening will save millions in lower chemeotherapy costs, fewer terminal care costs and added productivity to society from women who, without screening, would have died. Parkland doctors estimate in a screening project involving 10,000 women, those savings would add up to $2,850,000. That doesn't begin to count the value of a single life. Also, with more extensive use of screening, the cost of a mammogram should drop, much as the cost of the PAP smear did. When the PAP smear was introduced in the 1940's it was expensive and few doctors knew how to use it. It is now inexpensive, widely used, routine. Significantly, since introduction of the PAP smear, the death rate from uterine cancer has dropped more than 70 percent. I believe there are striking similarities between the state of the PAP smear twenty or thirty years ago, and the state of mammogram screening today.

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In conclusion, I urge you to make mammogram screening tests, which can save so many lives, available to women who otherwise could not afford them by providing Medicare coverage. I urge you to allow women to participate in decisions about their treatment, by enacting laws requiring doctors to inform breast cancer patients about all treatment alternatives. I urge you to recognize the importance of funding researchinto the number one cancer killer of women.

The Susan G. Komen Foundation will continue to try to add to the knowledge about breast cancer by supporting research projects. We will continue to fund breast cancer screening centers and to educate people about breast cancer. But a private foundation in Dallas cannot possibly reach the tremendous numbers of women whose lives will be cut short by this devastating disease. We need a partner, and your help is crucial. The need for quality breast cancer screening throughout the United States is desperate. I implore you to take advantage of this opportunity to save so many lives. Thank you.

THE PREPARED STATEMENT FOLLOWS

BACKGROUND: The Susan G. Komen Foundation for breast cancer research was founded in 1982 by Nancy Brinker as a memorial for her late sister, Susan Goodman Komen, who died of breast cancer in 1980 at the age of thirty-six. Susan was a remarkably active woman who was committed to her family, friends, and the community. It was her wish to help others similiarly stricken by this disease. By creating the Foundation, Nancy Brinker has made an on-going commitment to carry out her sister's wish to eradicate breast cancer.

The Foundation is an auxiliary of women who work toward the common goal of raising funds for the advancement of breast cancer research. One of the major goals of the foundation is to educate women about the disease so that higher recovery rates will evolve through early detection.

Another important goal of the Komen Foundation is to provide funds to finance important research projects directly related to breast cancer. In its first year, the Susan G. Komen Foundation raised over $50,000.

In 1983, the Foundation raised in excess of $130,000 and benefited the Breast Cancer Detection Center at Baylor University Medical Center, U.T. Health Science Center and M.D. Anderson Cancer Center. The 1984 recipients of grants in excess of $300,000 were the Wadley Educational Group, Presbyterian Hospital's Radiation Oncology Center, Baylor University Breast Cancer Detection Center and M.D. Anderson in Houston, and U.T. Health Science Center at Dallas.

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BREAST CANCER SCREENING - THE POSITIVE EFFECTS: Several factors should be considered in evaluating the cost benefits of breast cancer screening. The initial issue to be addressed is the cost of screening and secondly the savings generated from breast cancer screening.

The following items are accounted for in the cost of breast cancer screening. The first item is the charge of the mammogram. The average charge for a diagnostic mammogram is between $100 and $120. This cost can be lowered for a screening project which would have a significant impact on the cost effectiveness of breast cancer screening. The second item in the cost of a breast cancer screening is the cost of the breast biopsy generated by an abnormal mammogram. It has been well demonstrated by breast cancer screening projects that a significant number of "positive" mammograms represent benign disease. The generally accepted number for the rate of possitive biopsies is 20%. One out of five breast biopsies done for an abnormal mammogram will be positive for cancer. The other four biopsies will usually show fibrocystic disease. The cost of a breast biopsy done through a surgical day surgery unit generally averages $600 for the facility fee and $300-$400 for the professional fee, for an average cost including the hospital, operating and professional fee of approximately $900-$1,000.

The number of breast biopsies generated by a screening project would be four to five times the number of breast cancers diagnosed. These two items comprise the entire cost of a breast cancer screening project.

Using a sample group of 10,000 patients screened over a period of one year for the purpose of these calculations. Therefore, the initial cost of the project using the average community figure of $100 per mammogram, $1,000,000 for the mammography. The cost of the second item, the breast biopsy cost would be calculated based on the number of cancers that would be detected. Based on data from the Breast Cancer Diagnosis and Detection Project, 200 cancers would be detected. Therefore, 1,000 breast biopsies would be done to detect 200 cancers. So the cost in addition to the mammography cost of $1,000,000 would be the cost of 800 additional breast biopsies. It can be assumed that the 200 cancers would eventually have had a biopsy. So in addidtion to the $1,000,000 would be a cost of (800 X $1,000) or $800,000. Therefore, the total cost to screen 10,000 women over the 5 years is $2,800,000. This would yield a detection rate of approximately 200 very early breast cancers.

The next issue to be addressed would be the savings based on a breast cancer screening project involving 10,000 women. There are several assumptions that one must make in order to correctly identify all the areas of savings generated by this type of project. The first savings realized by diagnosing 200 early breast cancers would be due to the significantly decreased incidence of axillary lymph node metastasis. Based on a national survey performed by the American College of Surgeons, 33% of

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breast cancers currently diagnosed present with stage I disease (node negative). This compared to an 80% incidence of negative lymph nodes (Stage I) when cancers are diagnosed through a breast screening project. This then allows one to identify savings because of a much lower rate of adjuvant chemotherapy necessary. If we examine the 200 cancers that would be detected on the screening project, only 20% (40 patients) would require adjuvent post operative chemotherapy. This would compare to a 67% rate (134 patients) requiring adjuvent chemotherapy had the screening project not been performed. This results in initial net savings of the average cost of adjuvant chemotherapy for one year ($6,000) accrued for 94 patients (134-40). This figure calculates out to be approximately $540,000. (Based on a cost of $6,000 for 1 year of adjuvent chemotherapy.)

The second area of savings generated for society would be the benefit accrued by curing a greater percent of patients diagnosed with breast cancer. This also can be calculated for the 200 cancers detected in the model analyzed in this study.

At the Susan G. Komen Breast Cancer Screening Center at Baylor University Medical Center 8717 women have been screened from October of 1984 to October of 1985. 160 cancers have been detected. 60, 38%, of these cancers were in the non-palpable stage and the woman had no idea that she had breast cancer. 75% of the cancers detected had not metastisized to the lymph nodes which make the chance of survival much greater for these women. Screening saves money, but more importantly it saves lives.

The availability of breast cancer screening in a pleasant, friendly atmosphere makes a potentially threatening process much more palatable and easy for women to use. Screenings save money, but more important is the fact that it saves lives.

This does not even account for the value of a single life saved, as well as the amount of emotional trauma and suffering which is saved from the early diagnosis of breast cancer such as the avoidance of adjuvent chemotherapy.

This calculatiion is performed by assuming a cure rate of 85% for women who have Stage I cancer versus 40% for women who have stage II breast cancer. The table below outlines these savings.

Savings (based on 200 cancers diagnosed)

	Screening	vs.	Non screening
Cure Rate:	Node positive = 40 X 40% = 16		134 X 40% = 54
	Node negative = 160 X 85% = 136		66 x 85% = 56
Total Cured	16 + 136 = 152/200		54 + 61 = 110/200

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Therefore based on these projections of cure rates, 42 more women are cured because of screening mammography. This allows us to project several other significant savings generated. The two additional areas would be less terminal care required and the added productivity to society based on the addition of 42 productive women who would have died of metastatic breast cancer. These costs are calculated based on a recent estimate I obtained of an average of $15,000 to provide terminal care to a patient witih metastaatic cancer. Thus, the calculation for less terminal care would be 42 X 15,000 which is equal to $630.000.

The other area of savings would be added productivity to society based on 42 women contributing to society who would have died of metastatic breast cancer. The simplist way to evaluate this is to look at the productivity to society based on added tax revenue. The average age of breast cancer socccciety based on added tax revenue. The average age of breast cancer diagnosis is 55, which means that 10 additional years of productivity to society will be gained by screening patients. Using an average income of $20,000 and a tax rate of 20%, it is anticipated that over 10 years, an average person would contribute $40,000 in added tax revenue. Therefore, 42 patients would contribute $1,680,000 just in tax revenues as a result of screening. Thus these three areas of significant savings to society, less screening. Thus these three areas of significant savings to society, less adjuvent chemotherapy, less terminal care, and added productivity to society would total $2,850,000.

Another aspect to consider is that if the cost of mammography was reduced to $50, then money would be saved by screening mammography. Cost benefit analysis of this type have not been traditionally utilized in medicine due to the difficulty in assessing the value of an individual life. However, these calculations are necessary to offset the major criticism, as shown in the recent survey by the American Cancer Society, that only 39% of physicians practice screening mammography due to the cost of the mammogram. I believe there is a significant amount of professional ignorance in this area due to the lack of appreciation for the significant savings that can be accounted for when evaluating the cost of a screening project. The initial cost sounds very high; however, when one identifies the areas of directly dollar savings, one can see that the cost is saved in directly realized dollars.

INFORMED CONSENT IS ESSENTIAL: I encourange you to support HR 1579, the Breast Cancer Treatment Informed Consent Act of 1985 which requires states to enact laws requiring physicians and surgeons to inform breast cancer patients of alternative, effective methods of treatment.

Patients would have to be informed, both by means of a written summary and an oral explanation in layman's language understandable to them, of the available options and the advantages, disadvantages and risks associated with each procedure before surgery could proceed. States not enacting informed consent laws would be disqualified from receiving federal health assistance funds.

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Every year, hundreds of thousands of women undergo biopsies, not knowing whether they will awaken to find that extensive surgery has been performed. Fear of that "surprise" can inhibit breast cancer victims from seeking treatment altogether. Women need to know all the options available to them so that they can make their own, informed decision before treatment takes place.

A recent study by Dr. Bernard Fisher, published in the New England Journal of Medicine, indicates that lumpectomy and radiation can be as effective as the more radical and disfiguring total mastectomy in treating breast cancer in its early stages. These findings, underscore the importance of detecting breast cancer early so that it can be cured and patients can have as many options as possible.

If my sister had had informed consent she may have been able to survive breast cancer. I was knowledgable and sought aggressive treatment and I am here to tell you about it and what needs to be done.

Informed consent will require physicians to be just that - informed. Their patients will be asking more questions and they will want to be able to give accurate answers. This will benefit both parties and save lives and personal suffering for patients and their families.

APPENDIX

FACT SHEET

PURPOSE AND GOALS: The Susan G. Komen Foundation is an auxiliary of women who work toward the common goal of raising funds for the advancement of breast cancer research. One of the major objectives of the Foundation is to educate women about the disease so that higher recovery rates will evolve through early detection.

PRESIDENT: Linda R. Cadigan

ACTIVITIES:	1982	* Women's International Polo Tournament at Willow Bend Polo Club, Dallas
	1983	* Annual Awards Luncheon, Dallas
		* 5K Run for Women, Dallas
	1984	* Annual Awards Luncheon, Dallas
		* Breast Cancer Seminar, Dallas
		* Underwriter's Auction Party, Dallas
		* 5K Run for Women, Dallas
		* Membership Tea, Dallas

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1985

* Underwriter's Auction Party, "Race for the Cure, Lap 2", Dallas
* Membership Tea, Dallas
* Annual Awards Luncheon, Dallas
* 5K Run for Women, Dallas
* Breast Cancer Seminar, Dallas

FUNDS DISTRIBUTED SINCE 1982: $500,000

ORGANIZATIONS WHICH HAVE RECEIVED FUNDS FROM THE FOUNDATION:

* Breast Cancer Detection Center, Baylor University Medical KOMEN Center, Dallas
* Dr. Ellen Vitetta, Department of Microbiology, The University of Texas Health Science Center, Dallas - 1983 Taittenger Award
* Dr. Gary Spitzer, Department of Developmental Therapeutics University of Texas System Cancer Center, Houston
* Dr. Marvin Stone, Breast Cancer Detection Center, Baylor University Medical Center, Dallas
* Dr. Ellen Vitetta, Dr. Jonathon Uhr, Department of Microbiology, The University of Texas Health Science Center, Dallas
* Dr. Gary Spitzer, The University of Texas System Cancer Center, Houston
* Wadley Institutes of Molecular Medicine, Breast Self-Examination Program
* Planned Breast Cancer Detection Center, Presbyterian Hospital of Dallas
* Dr. Adeline J. Hackett, Peralta Cancer Research Institute
* Dr. George Blumenschein, Arlington Cancer Treatment Center - 1984 Taittenger Award

TAX STATUS: The Foundation is certified by the IRS as a 501(c)3 and the tax number is 75-1835298.

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BREAST CANCER FACTS

* Approximately 100,000 women in the United States will develop breast cancer this year.
* Breast cancer is the most common cause for mortality in women between the ages of 35-54 in the United States. Cancer is the second leading cause for death in women in the United States.
* One out of ten women in the United States are at risk for developing breast cancer during their lifetime.
* Early detection of breast cancer improves the chances for surgical cure. Mammography is the most sensitive technique for early detection, but does not eliminate the need for physical examination.
* The combination of physical examination and mammography as screening techniques for breast cancer - when applied regularly to a population of women - will decrease their mortality rate from breast cancer.

FACTS ON THE COSTS AND SAVINGS FOR A MAMMOGRAPHY PROGRAM

Cost of Mammograms ($100/Mammogram) for 10,000 women (the cost can be reduced as the volume is increased.)	$1,000,000	COST
Cost of breast biopsies ($1,000/biopsy) for 1,000 women (one out of five of these will be positive for cancer.)	$1,000,000	COST
If you screen 10,000 women/year 1,000 biopsies would be necessary and 200 early cancers would be detected. The total cost would be	$2,000,000	COST TOTAL
Adjuvant chemotherapy costs $6,000/year. If you do not screen, 134/200 patients would need chemotherapy. When you screen only, 40/200 patients need chemotherapy therefore you save the cost of chemotherapy for 94 patients	$ 540,000	SAVED

Stage I breast cancer cure rate is 85%

Stage II breast cancer cure rate is 40%

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Therefore, when you screen, 42 more women are saved. If these women had not been cured, the cost of terminal care is approximately $15,000 per person, saving over $600,000 when they are cured.	$ 630,000	SAVINGS
These 42 women have 10 added years of economic productivity and the average person contributes $40,000/10 years in tax revenue, therefore, these 42 women are cured, they will pay taxes over the additional 10 years totalling	$1,680,000	SAVINGS
	$2,850,000	TOTAL SAVINGS
	$ 850,000	NET SAVINGS
Therefore, the total savings greatly exceeds the cost of a screening project. If increased volume reduces cost of mammography by 50%, then the net savings of the project will be even greater.	$1,850,000	POTENTIAL SAVINGS

Ms. OAKAR. Thank you very much, Nancy, for your excellent testimony and for the great work that you are doing with your foundation. You can't reach everybody, but it's a great beginning. I know you have probably saved a lot of lives because of it.

Let me ask my chairman if he has any questions.

Mr. PEPPER. Yes, I have just a few inquiries.

This is a tragic situation. As you know, some 38,000 to 39,000 women in the United States die every year of breast cancer. We did a survey and made some findings, and I want to ask these witnesses whether or not they think these findings are generally true.

The subcommittee found that the reason so many women do not receive the benefit of detection or new preventive technologies is directly related to the awareness, the affordability, and the availability of these new screening and detective procedures. First, we found that most women are not aware of screening techniques available to them, which, if employed, could substantially reduce their risk of devastating bouts with breast cancer, or minimize surgical intervention required to halt its progress. Testimony today discloses the need to alert women to choices they have available to them.

Second, we found women can't afford most preventive measures currently available for earlier detection and treatment of breast cancer. Medicare will not pay for most preventive services like early detection of breast or other cancers. And Mrs. Brinker has emphasized here that it is the early detection and early efficacy of the treatment that gives the woman who has breast cancer a better chance to live.

Third, we found that for those women who do want to take preventive measures—to get screened regularly and obtain less medical surgical intervention—availability of screening and detection centers, outside of a hospital setting requiring physician referral and so on, is almost nonexistent.

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Mrs. Brinker, you in the most commendable way have added very meaningful facilities in Dallas for women who have discovered breast cancer or wish to prevent it. Without those facilities that you have added, what services would have been available for preventive or curative treatment of women with breast cancer in Dallas?

Mrs. BRINKER. Because Dallas, Senator, is a big city, there are facilities available. The problem is reaching them and, again, affording them. What we have done is created a nonthreatening, easy, low-cost way so that we are basically aiming ourselves to the woman's needs and also creating an environment of a place where she knows she can go for these specific problems. It would be much more difficult without the awareness and the facilities we have created to have that happen.

So, we definitely have added a dimension that even in a city of 1 million people did not exist.

Mr. PEPPER. Do you know of any governmental facility in Dallas to which any woman who suspects that she has cancer of the breast may go?

Mrs. BRINKER. The only governmental facility is our county hospital at Parkland, where, of course, she could go. But what we have done is, we have had to come in and add, at a half million dollars, this whole breast service department. Prior to this, they were being taken in with the regular population, and we did not have the facilities there. And the county couldn't fund them. The Federal Government certainly couldn't fund them. The city couldn't fund them. And the State couldn't fund them. So, the only place in Texas we really have other than some of the endowments provided by some of the private hospitals is at M.D. Anderson Cancer Center in Houston, which is 400 miles from Dallas.

Mr. PEPPER. Well now, I think of the various cities and towns and villages all over America where women may be faced with this critical discovery. What is the individual going to do? If she just goes to a doctor, everybody may not have a first-class cancer clinic or hospital or other facility equipped to deal with the problem effectively. A lot of women don't have the money to pay the doctor.

The reason I was pursuing that inquiry is because Senator Gore—and I know Ms. Oakar is supporting it, as she is all other good legislation pending here in the Congress—and I have introduced legislation with respect to Alzheimer's disease, the fourth largest killer in the United States now. It has become almost impossible for family members to take care of a victim in the family. After a little while, the Alzheimer's patient becomes so exacting you have to be with them every minute, they tell me, while they are in that advanced stage of the disease.

We have introduced legislation to set up 20 treatment and research centers all over the United States to deal with Alzheimer's disease. I was wondering if we could ever get the United States to feel that it has a conscience again and some compassion in its heart—wouldn't it be a very desirable thing to have some sort of centers? If a community can put together a breast cancer center that the Government would approve, that is suited to take care of the women that have that danger, well and good. But communities need help in setting them up. If centers were established and their

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existence made known, these ladies would know where to go for prevention.

I was pleased to see Ms. Nash had gone to an HMO. I am hoping that the HMO system is going to be helpful. Apparently you found good care there—that lady doctor that worked with you apparently was competent. And you had the advantage of preventive care.

Ms. NASH. Yes.

Mr. PEPPER. They wanted to check you while you were healthy. They would rather help you to keep from having the disease than to pay for your having it, as it were.

So, I hope, Ms. Oakar, that we can give some consideration to establishment of some sort of a screening facility, and I am sure you and I have already talked about the basics of such legislation. I hope we can develop something like that.

Do you all think that something like that would be desirable? Do you, Ms. Chaskes?

Ms. CHASKES. I believe so.

Mr. PEPPER. Mrs. Brinker, we want to commend you on what you have done individually to make life better for women in your area. You have propably helped save many lives. May the Lord extend your reach far afield.

Thank you very much.

Ms. OAKAR. Let me just add, Senator, that I think what the witnesses have mirrored today is, and what I think the hearing is all about is, that we want to allay some fears about the disease. And here we have three women who have the disease or had the disease and have been treated for it apparently successfully. And that's the good news, that it's treatable, particularly when you catch the disease in an early stage.

Mr. Hennessey has given us a great service, and in your wife's memory I don't think you could do anything more profound, because you told us of your personal experience. Possibly—we will never know for sure, and I think that should be in your mind as well—if she had had an earlier detection, like your sister, Nancy, you know, she may have survived that disease. So, you told us that very, very moving story.

But we are saying something more, and I think that's why you have your research center going along with the prevention center in Florida. And HMO's do do that kind of service as part of their health plan. I wish other insurance policies would cover a free checkup, because it makes so much sense; and we are trying to put that in our legislation for Medicare. It's just being penny-wise and pound-foolish. But what we are seeing here is that, beyond the prevention stage, we want a cure for cancer. And we as the American Government ought to be channeling our energies in that direction. There are so many great people that we are going to hear from who are working on this research, but they can't do it alone.

I guess my question overall briefly would be, do you think the Government has a responsibility? We have these private groups that are fabulous. But does the Government have a responsibility to put forward the service of role model in research? Should we be doing more in that area? Anyone who wants to touch on it, I would be happy to hear from them.

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Mr. HENNESSEY. In dealing with my wife's illness, I think everything I was trying to deal with was prospective. And until I was asked to testify and give my own experiential observations, I don't think I looked retrospectively about the implications of some things.

But I really think education is the first step for people to make responsible decisionmaking. And I think health care and the relationships between patients and experts is much more integrative than it has been. I think that is a tremendous advance. But I think education is so important to encourage people to know more and to engage in responsible decisionmaking.

Mrs. BRINKER. I just wanted to respond to that for a minute, Mary Rose. I think that the Government very much has a responsibility. But perhaps more than just saying we have a responsibility, a responsibility has to be just not only monetary but one perhaps of taking the leadership role in coordinating efforts that are privately done, done by the Government, done by insurance companies, in other words, maybe being a little bit in a leadership position.

I think there's an awful lot of money out there privately, and there's a lot of money that could be directed and channeled privately, such as in projects we are doing, public-private partnerships in areas. But I think we have to recognize the problem and direct our attentions to the goal.

Ms. OAKAR. Does anybody want to add?

Ms. CHASKES. I think she said it all.

Ms. NASH. I would just like to say one thing about a word I had mentioned, Senator Pepper mentioned, and I think somebody else did: the word "compassionate". I feel it would be a compassionate response of the Government to its people to promote, encourage, and fund projects of this kind.

Ms. OAKAR. One of the things that you pointed out that may not come out in the testimony today has to do with the fact that you also had reconstruction with your mastectomy. A lot of people don't realize that, when you do have that kind of plastic surgery, or whatever the common terms are for it, it is really fantastic. And women don't have to worry about looking maimed and all that sort of thing anymore, because you can have successful reconstruction with a lumpectomy or even a mastectomy. I think that is what we have to do to get people not to be afraid of the disease. You have got to tell them what all the options are.

Ms. CHASKES. There are lumpectomies where you don't need reconstruction, which I did. It was very, very small because it was detected early.

Ms. OAKAR. You didn't even have to have it. You probably wouldn't even know you had that surgery, right?

Ms. CHASKES. That's right.

Ms. OAKAR. That's great.

Thank you all very, very much. It is a pleasure to have you.

Mr. PEPPER. Thank you all. You were a very fine panel, and we appreciate your being here.

Ms. OAKAR. We are going to hear from our next panel now.

What we want Dr. Thomas to do is explain, if he will, a little bit about what a mammography is.

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Doctor, we want to pick it up for the benefit of the women across the country and their families. Thanks to the media's interest, and I want to thank the media for being here, we want to make sure that they can hear you as well.

Dr. THOMAS. What we have here are mammograms, very current mammograms—in fact, the lower pictures were just taken yesterday at Columbia Hospital for Women right here in Washington——

Ms. OAKAR. Doctor, can you possibly bring that over here? Is that possible, to get a little closer to the mike? We want women across the country to hear you, too. It is really important that you be heard.

Dr. THOMAS. The blue picture which I have brought here are mammograms that are printed on paper using the Xerox technique. They are a little better for display.

I want to emphasize that mammograms can and are to be taken using x-ray film. Mammograms made on x-ray film are much less expensive than the Xerox mammograms, and the amount of radiation that the patient receives is much less than with Xerox mammograms. In a screening situation, because of these two facts, film will probably be used rather than the Xerox process.

The first patient that I show here, the first x rays were taken—the patient was referred. She is 43 years old. The patient was referred by her internist for a routine mammogram. She had a mammogram when she was 40. There was 3-year interval.

This is difficult to see, even for the radiologist with a magnifying glass. So, I wouldn't expect it to display to the group. But there were some very fine calcifications in the upper outer portion of her right breast that were not present 3 years before. Her internist was urged to have her see a surgeon, get a surgical consultation. The surgeon examined her, could not feel anything abnormal. But he advised her to go to the hospital where the radiologist placed a very fine wire with the tip right there where the most suspicious calcifications were. Then she was taken to surgery. The surgeon, using the wire for a guide, took out this small amount of tissue with the end of the wire. We took a picture of this specimen of tissue, showed that he had gotten the suspicious calcifications.

Then the specimen was sent to a pathologist who confirmed the diagnosis of cancer October 22.

Now, the way these patients are treated, the patient will be advised of her various options. I don't know how she is going to choose to be treated.

Now I would like to show this case over here.

Ms. OAKAR. Doctor, while you are doing that, in other words, because of that mammogram there was a detection that even her surgeon may not have felt, or she would not have felt, it was so small. And that's the value of that mammogram, isn't it?

Dr. THOMAS. Yes. This is what we call an occult carcinoma. It could not be palpated by the patient, by the radiologist, or the surgeon.

The second case that I show here is also a patient who was referred in for routine mammography. This patient was 71 years old. A small suspicious area was found deep in her right breast, completely nonpalpable. She, too, was referred to a surgeon. This lady went to Sibley Hospital here in the District. A wire guided localiza-

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tion of the cancer was accomplished. The cancer was removed. This cancer was point one half a centimeter, about a quarter of an inch in diameter. This lady is one of them who elected to be treated just with lumpectomy and radiation. She came back in recently.

This is the normal left breast. This is the right breast, which had the lumpectomy and the radiation, with pretty good cosmetic effect.

If there are any questions about this——

Ms. OAKAR. Just explain procedurally what one does to have a mammogram. I bet a lot of people have never had one. I remember the first time I had one. I was scared to death. When it was over, I said, you mean it's over? I couldn't believe it. So, maybe for the benefit of the people here, you could just explain procedurally how long it takes and what it is, and that sort of thing.

Dr. THOMAS [continuing]. The procedure for the routine mammogram has been speeded up and become much more efficient in recent years due to the use of what we call dedicated x-ray equipment. The patient no longer has to lie on a very uncomfortable x-ray table and roll around. Actually, the examination is done with the patient standing up. Two views are taken of each breast in a routine fashion. The examination in our office takes between 5 and 10 minutes.

Mr. PEPPER. Excuse me, Doctor. You made the observation a moment ago that you didn't know what the lady was going to choose to have done. Well, you know, she's a layman. I don't imagine she is an expert in cancer. How is she going to know what to ask somebody to do?

Dr. THOMAS. Senator Pepper, first I want to say I am a radiologist, not a surgeon or a chemotherapist or even a radiotherapist. But the way I understand it, the patient has her various options explained to her. She can have what they call the modified radical operation, where the entire breast is removed. She can have an operation where they just remove the lump, or maybe they have removed the lump completely during the biopsy. And then she can have radiation therapy. And whether or not she has chemotherapy——

Mr. PEPPER. Excuse me. I would assume that she would say to the doctor, I want to live. I don't know what I need to have done. Tell me what you think I need to have done. I want to try to remove this cancer if possible. I would like to have the least radical operation I can have, of course, if I can safely have it.

I am just thinking about the dilemmas presented to these patients who go in after being diagnosed with cancer. They have to make all these decisions. They don't know what to say, do they?

Dr. THOMAS [continuing]. Well, sir, I am going to refer this question, if I might, to some of our radiotherapists or surgeons who are here and maybe even to the patients who have been through this dilemma that you describe.

Mr. PEPPER. That's good.

Ms. OAKAR. If the chairman will yield on that, we are going to hear from Dr. Lerner, who, along with other fine people, has done a very interesting study which shows that women may have options. And they can intelligently, I think, make a choice about their options. So, I think we are going to answer that question in a

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minute, Doctor. And Dr. Strax as well, I think, might comment on that.

Mr. PEPPER. Well, I have always heard of the greater wisdom of women, so that's an example of it.

Ms. OAKAR. Thank you. Thank you, Doctor.

Our first witness in this panel is Dr. Philip Strax, the director of the Guttman Breast Cancer Detection Center.

If we can confine the testimony, it will give us a little more time for questions. So, you can submit the entire statement for the record.

PANEL THREE—PRIVATE AND VOLUNTARY RESPONSE: CONSISTING OF PHILIP STRAX, M.D., DIRECTOR, GUTTMAN BREAST CANCER DETECTION CENTER, NEW YORK, NY; WILLIAM E. POWERS, M.D., CHAIRMAN, DEPARTMENT OF RADIATION ONCOLOGY, WAYNE STATE UNIVERSITY SCHOOL OF MEDICINE, DETROIT, MI; HARVEY J. LERNER, M.D., CHAIRMAN, DEPARTMENT OF SURGERY, GERMANTOWN HOSPITAL AND MEDICAL CENTER, PHILADELPHIA, PA; DIANE BLUM, DIRECTOR OF SOCIAL SERVICE, CANCER CARE, INC., NEW YORK, NY; ROSE KUSHNER, EXECUTIVE DIRECTOR, BREAST CANCER ADVISORY CENTER, KENSINGTON, MD; AND MARTIN A. THOMAS, M.D., AMERICAN COLLEGE OF RADIOLOGY, WASHINGTON, DC

STATEMENT OF PHILIP STRAX

Dr. STRAX. Senator Pepper and Ms. Oakar and members of the committee, I thank you and congratulate you for your continued and sustained efforts in furthering the mission close to all of us: saving the lives of women from breast cancer.

My remarks are divided into several categories.

First, the problem. Breast cancer is one of the most, if not the most, serious medical problems women in this country face. It is the No. 1 cancer at any age. One fourth of all cancers in the female is in the breast. It is the No. 1 cause of death from any cause in women age 39 to 49. The risk for getting the disease increases with age. A woman at 70 has six times the risk of having the disease as a woman at 40. Some 20-odd years ago, as you heard, it was said that one in 20 women will develop breast cancer. Today the ratio is 1 in 11. And there has been a particularly steep rise in women under the age of 50. It is no longer unusual to see the disease in women under 35 or even under 30. Every 5 minutes a breast cancer is diagnosed in this country. And every 15 minutes a woman dies of the disease. In spite of the advances in treatment, not more than one out of three women is alive and free of disease 10 years after diagnosis. And we have had a stationary death rate from the disease for the past 40 years. Just as many women die of breast cancer in proportion to the population as did many years ago.

Second, a remedy. We still don't know the cause of breast cancer, nor do we have a method of prevention. We don't know how to cure the disease when it has spread beyond the breast. And this is the usual case we meet in general practice. But we do know that, if we use our present know-how to detect the disease when it is still localized to the breast, 9 out of 10 women will be with us 5 or even 10 years later compared to less than 50 percent when the disease

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has spread beyond the breast. We have evidence from the health insurance plan study carried out under the auspices of the National Cancer Institute for the past 20 years that examining women when they are presumably well will result in the saving of at least 30 percent more women than without the examination.

We also know that cancer of the breast is the only cancer for which we have widely accepted statistical proof that early detection results not only in increased survival but in actual substantial saving of lives. We do know also that examination for proper protection must involve not only expert palpation—but also modern, well-performed mammography, plus teaching breast self-examination at time of examination to detect the cancer that may turn up after a negative examination. Mammography does not pick up all cancers. You have got to have the clinical examination in addition to finding those cancers that you cannot detect on mammography. We have the means to save most of our women from breast cancer. Why then haven't we used our effective methods of protection? What are the obstacles in our way?

Third, the obstacles. For many years we have known that the breast is sensitive to x rays. In 1976, a commotion developed and statements were made and reported in the media that mammography which uses x rays might in itself produce breast cancer and that the hazard might be greater than the benefit. Over the years, it has been emphasized by the radiobiologist, the expert on the effect of x rays on the body, that such hazard is related to the dose of x rays and the age of the woman. The dose of x rays used in modern mammography is now and has been for many years so low, less than one-fiftieth of 1 rad to the middle of the breast, that authorities consider the risk of even periodic mammography over many years to be negligible and probably not even measurable. Furthermore, the risk of x rays to the breast has been considered particularly unimportant to women over the age of 35, when cancer is most likely and when screening is done. It is of interest that 16,000 women were examined with mammography in the health insurance plan study about 20 years ago with total doses far higher than would be given to women with modern techniques, even when given periodically for 30 years; and no unusual increase in breast cancer has been observed.

Another obstacle has been the statement that no benefit has been noted in screening women under 50 years of age. Actually, there has been a benefit which is increasing with time, although not as great perhaps as in women over 50. It is also the considered opinion of statisticians from the American Cancer Society as well as from several prestigious medical centers that screening has and will continue to produce important benefits in all women over 40.

A more important obstacle relates to cost. Breast examinations, including mammography, as done for women who come to the physicians with a possible breast condition, usually cost somewhere between $150 and $200. However, we also know that a screening center, where large numbers of women can be examined in an efficient manner under the auspices of a nonprofit organization, can do the complete study for less than $50. That includes palpation as well as mammography. A freestanding center, especially with the support of community women, using the services of dedicated phy-

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sicians and interested paramedical personnel can be made self-sufficient at that rate, if the proper number of women can be motivated and stimulated to have regular examinations.

The Guttman Institute in New York City has examined periodically over 110,000 women in over 330,000 examinations in the past 18 years without making any official charge. A small charge of $45 is now contemplated for those women who can afford such a charge. A satellite center, the Strax Institute in Fort Lauderdale, FL, has been in operation for 5 years. A fee of $35 has made it possible for the institute to be self-sufficient, with the support of women's groups, as you heard, like the United Order True Sisters, which supplies volunteers and raises funds to help keep the operation going. Well over 1,000 women are examined per month at that facility.

If it were possible for the Government to contribute directly or encourage third-party payers to help in the establishment and support of centers similar to the ones I mentioned, there is no doubt in my mind that the concept of mass screening to save the lives of women through early detection could be spread throughout the land. Such obstacles as training medical personnel in the modalities used and setting up quality controls for the examinations can also be overcome easily if the desire to do so is present.

May I talk about future horizons? To make mass screening even more effective than it is today, we need to know and be able to detect a true high risk indicator so that we could concentrate our efforts on those who have the greatest need. Today, three out of four cancers are detected in women who have none of the usually mentioned risk factors. We must consider all women over 35 at risk for having or getting a breast cancer. A project is now underway under the auspices of the New York University Medical Center, funded by the National Cancer Institute, in cooperation with the Guttman Institute, the Strax Institute, the Imperical Cancer Research Fund in London, and the Netherlands Cancer Association in Amsterdam, which is looking into the endocrine, environmental and even the psychological factors in breast cancer. This prospective study may tell us within the next 5 years which women are most likely to develop breast cancer. Such a study may also well lead to prevention of the disease through correction of hormone abnormalities or avoidance of the risk factors connected with the diet.

But right now our greatest need is to make it possible for the women of this country as well as elsewhere to have the facilities available in their communities which will offer a complete, thorough breast examination so the disease if present can be detected in its most curable stage. And these examinations should be available under circumstances which make it possible for all women of all economic levels to take advantage of them.

Thank you very much.

Ms. OAKAR. Thank you, Doctor.

We are going to hold for questions until the end of the panel.

We would like to welcome Representative Helen Bentley from Maryland, who is joining us. Thank you, Helen, for being here.

Our next witness is Dr. William Powers.

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STATEMENT OF WILLIAM E. POWERS, M.D.

Dr. POWERS. Thank you very much.

I practice radiation therapy and will this year see approximately 260 women with breast cancer, new patients that I hadn't seen before. Unfortunately, three-fourths of those patients will present to me an incurable state of their chronic disease. One-half of the women are of age for Social Security when they present. Three-fourths of them will be Social Security beneficiaries during that chronic disease, which is spread over a number of years.

The cost of failure in these women is probably about five times as much as the cost of cure of a woman with breast cancer would have been if the cancer had been detected early. The numbers you used and in the College of Radiology statement are numbers that I prepared several years ago. The numbers are greater now than they were at that time. It is closer to $25,000 for a cured case and five times that for a failed patient.

Our interventions are becoming more costly in these patients who fail. They do prolong life. They do prolong useful life. But the fact is that there is an inexorable progression of the disease once it has been metastatic to other than the skin.

We attack the problem at the wrong way, unfortunately, because we are swinging too late. What I want to do is go to a patient and say: When you come to me, you're going to be treated for cure. You have a curable disease.

Now, let me assure you that most women when they hear they have breast cancer but it's curable do not hear those last words. I make a tape recording for the women so they can take it home and listen to it afterward. They literally are so shocked, and it doesn't matter how many times they have heard it before. They are shocked out of their skull because it is a threat to self. It's a threat to life. It's a threat to their resources. It is an unbelievable threat to these individuals. They have lost much of control that each of us holds dear in our life.

I ask that the women be given an opportunity to have a part of their control in terms of an explanation of the alternatives available to them. I will express my view of it and Dr. Lerner his. The evidences are accumulating that there are alternatives to a mastectomy. We all agree that it is necessary to examine the propensity of the tumor to spread. We all agree that the tumor must be removed in its entirety. There is reason to believe that it is of benefit to the patient to treat the local area dependent on characteristics with either surgery or radiation therapy, sparing the breast if possible, reconstructing the breast if a breast-sparing operation is not possible.

By the way, reconstruction is just not paid for by many policies and many programs. And that's a major disservice to women.

I am interested in women having a milieu that breast cancer is a curable disease and that they can be promised that, if they do something early, something life defying, something a privilege, get a mammogram and get an examination of their breast; and if they have a breast cancer found, they are not going to be punished by an operation they deem destructive. I don't deem a mastectomy destructive but many women do.

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Mr. PEPPER. I don't want to break the rule about waiting until all the witnesses are finished, but I want to ask this. At what time should the woman seek medical help?

Dr. POWERS. I think, sir, that a woman should seek medical help if she personally finds anything in her breast for sure, and I think——

Mr. PEPPER. At the first appearance of any lump?

Dr. POWERS [continuing]. Yes, sir. But I think, in addition to that, that women owe it to themselves at age 50, or with other risk factors, family history or other, of having a mammogram and having periodic self-examination and periodic examination by a physician and the radiographic confirmation. We know that we can't feel everything, and we know the radiograph doesn't show everything. We need both.

I suggest that, if women have the opportunity to be offered an alternative, which is to them preferable in that it saves their breast—I don't think it's as important to men as it is to women, but it is women who suffer from this process—to save their breast if they want it. I offer the woman several things: One, a tape recording at the time I discuss the alternatives with her. And I try to discuss all of the research that has been done and the accumulated experience.

I offer the document that was prepared in the State of California as a requirement to give to women to allow them to participate in the decision. And I explain to the women that it isn't necessary they explain, that they answer that in the next 30 seconds, but they have an opportunity for a second opinion, and they have an opportunity to do some discussion.

Now, the alternatives therapy rewards the early detection that is available for the patient and the woman has a part of control. This all depends on the woman seeking the early detection and the early detection process being available. We have the process. It's just not available to these older women who already are in straitened circumstances.

I believe that we need prevention in the future but intervention today in a societal manner that will solve this problem.

Thank you for the opportunity.

I'm sorry, I forgot one other thing.

Every one of these women who has one breast cancer has been told that she's at risk of a second breast cancer in her opposite breast and must have examination. Now, if she does not have the resources, you have put her in the terrible quandary of being told, you're at a greater risk than somebody else but we're not going to do anything for you. And I beg that we do something for these women.

Thank you for the opportunity.

[The prepared statement of Dr. Powers follows:]

PREPARED STATEMENT OF WILLIAM E. POWERS M.D.

The more than 260 patients that I will see with breast cancer this year represent the tremendous variability in women—many ages, many personalities, many physical and mental states and the great variability in breast cancers—different histology types, different growth rates of tumor and different responses to the tumor by the patient. There is however in all of these patients a commonality in the threat to the self of the woman, a threat to the woman's life and a probability of expenditure

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of a major portion of her resources of herself and her family in order to care for the dread disease.

One-fourth of these patients present with early cancer with hope of saving of life and breast by local excision of the tumor and radiation therapy with preservation of the breast. In these patients and other patients with early breast cancer the combination of surgery and radiation presents to the woman an alternative that is not a threat to her self image and is thus a reward for the early discovery of breast cancer. Too often in the past women expecting the only alternative of loss of their breasts with a mastectomy have a sense of punishment for discovering the disease and thus delay a visit until the tumor is large and may have spread. In fact, approximately 10% of the patients I see have ignored or neglected their very evident tumor until it was so large and extensive that surgery of any type was impossible and the patient is presented for radiation therapy and chemotherapy for control of an incurable disease.

Two-thirds of the patients I see represent women who are treated for recurrence of their breast cancer, often for the second, third, or even greater number of recurrences over the years.

Breast cancer in these women is a chronic disease that often spans from two to twelve years under treatment and is likely to require continued care for the patient and her cancer until her death. This chronic disease phenomenon is particularly true in older women where the cancer is often slower growing, slower to manifest evidence of spread but once disseminated nearly inexorable in its final progression course.

The long term existence of this disease and the multiple courses of expensive treatment require a major expenditure of the patients remaining resources at a time when the patient is least able to handle these particular great losses.

Each of the women who is free of disease after the initial treatment also face the threat of cancer in the opposite breast at a rate more than double of other women and thus lives in constant concern for an adequate early discovery in care of the possible second tumor.

I believe with many of my colleagues that breast cancer is more curable now than in the past because we have:

(A) the possibility of early case finding by self examination and mammography as well as the stimulus to the woman to participate in this early case finding because of a reasonably attractive alternative—cancer cure with preservation of the breast and

(B) cure of the patient with breast cancer and subsequent follow-up as well as death due to another cause is cheaper than death due to the failure of breast cancer with multiple courses of expensive treatment and long term care.

Therefore I recommend:

(A) Legislation to provide a mechanism for women to have examinations detect breast cancer as early as possible and

(B) Legislation to result in the information of women of the alternatives of treatment.

Ms. OAKAR. Thank you, Doctor.

Your figures that you supplied the committee are just so interesting, about how much more it would cost for failure than it does to prevent it. I mean, it just doesn't make sense that we don't do the right thing in that area.

Dr. Harvey Lerner, thank you so much for being here.

STATEMENT OF HARVEY J. LERNER, M.D.

Dr. LERNER. Thank you. I will submit my written report and speak a little extemporaneously.

I would like to say first that cancer really is a word and not a sentence. When we hear the word, we have this whole thought process. It's a word.

My mother died a slow agonizing death at home after a long cancer illness. One out of every three Americans born in 1985 will develop an invasive cancer at some time during their lifetime. I think of cancer as an epidemic in this country. One out of every 11 American women, as you have heard, will develop a cancer at some

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time during her lifetime. The death rate from cancer in this country has not changed during the past 50 years despite bigger operations, antibiotics, transfusions, intensive care units. You name it, we can do it for them. It hasn't changed.

I would like to just briefly review some of the surgery that has gone on and some of the clinical trials and some of the biology.

Halsted in 1894 popularized a mastectomy which removed the chestwall muscles. Somewhere around 30 or 40 years ago, some bigger operations were devised; called an extended radical mastectomy, which in addition removes the nodes between the ribs, and something later called a super radical, which removed part of the chestwall, if need be, and the nodes from above the clavicle. These have not really changed survival.

A trial out of Italy comparing an extended radical, removing the nodes between the ribs, to a standard radical did absolutely not change survival. If women had both sets of nodes involved by cancer—and this is everyday operable breast cancer—the 10-year, disease-free survival was about 3 percent. So, bigger surgery really hasn't changed survival. What we do locally only affects what happens locally. If the cancer is already a systemic disease, it will not affect the outcome. With untreated breast cancer, about 5 percent of women will survive 10 years.

The national surgical adjuvant breast project [NSABP] was the first to perform randomized clinical trials in this country and has provided some very important data. If women have negative nodes at 10 years, they probably have a disease free survival of about 65 percent. If they have four or more nodes involved by tumor, it's less than 20 percent; it's less than 13 percent.

Other trials have gone on by the breast project in which the ovaries have been removed or postoperative radiation therapy given. These did not change survival. A very important trial was performed a little over 10 years ago in which women were randomized prospectively to a standard mastectomy which removed the glands beneath their arm; to a mastectomy with radiation therapy to the glands beneath their arm, above their clavicle, and between their ribs; or just a mastectomy that was performed for women who had clinically negative nodes. At 10 years, there was no difference in survival or failure rates. The overall 10-year, disease-free survival for that group was about 47 percent for clinically negative nodes.

So, there is an error in clinical staging between what we feel and what we find under the microscope which runs somewhere between 25 and 40 percent.

Another major trial that was performed was a King's Cambridge trial, with big numbers. We require big numbers in clinical trials to have meaningful data. They had over 2,200 patients. All women had stage I or stage II breast cancer, meaning the nodes may have been clinically involved or may not have been clinically involved. All women had a mastectomy with no surgical treatment to the nodes. One-half of the women had their lymph nodes irradiated. The other half were just observed. They were referred to as a "watch group." If the nodes progressed in size, then they received treatment.

Ten years later, there is no difference in survival.

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The next most important biologic trial is protocol six out of the breast project. It was based somewhat on some earlier trials in Europe of less than a mastectomy. Protocol six was a randomized, prospective trial and had quality assurance and peer review. It performed a standard mastectomy compared to a lumpectomy, or a partial mastectomy, or a partial mastectomy with radiation therapy to the breast. All three groups of women had the nodes surgically removed for staging.

At 5 years, there is absolutely no difference in survival. It is anticipated that the 10-year results again will be equal. If the woman did not receive radiation therapy to her breast, then the failure rate in the breast approached 30 percent at 5 years. If she received radiation therapy to her breast following a lumpectomy, then the failure rate ran in the neighborhood of 7 percent, which is about the failure rate locally following a mastectomy.

Other reviews, long-term reviews, because cancer is not a 5-year disease or a 10-year disease, it is a lifetime disease, have reported that most women turn to their doctor and appear with a cancer that is local or regional in about 90 percent of the time. But of 100 percent of the women who appear, that they will die from cancer is estimated at 80 percent. Even if you survive 15 and 20 years free of disease, you still have a death rate from breast cancer twenty-fold greater than the normal population. So, the biology of breast cancer is something of value.

In breast project data, if women have their cancers detected between 1 and 9 millimeters, very small, 22 percent already have lymph node metastases. And almost half of those have four or more nodes involved.

Dr. Walter Baver has demonstrated that, by the time a breast cancer is 6 millimeters in size, 90 percent of the women have already developed node metastases. You are biologically fortunate or you are biologically unfortunate. Cancer really is a long-term process. It's not something that befalls you yesterday. It takes a long time to develop. It remains as a noninvasive cancer for a period of time. Hopefully, we will discover it then. Once a cancer invades, then almost as rapidly as it invades, it can disseminate.

In terms of doublings, 10 doublings is a thousand cells. I am talking about exponential doubling going from two cells to four cells, to eight cells, and so on. Twenty doublings is 1 millimeter, the size of a dot of a lead pencil. Thirty doublings is 1 centimeter, about the size of the tip of my little finger, looking end on. The average cancer in America is detected at about 3 centimeters, 35 doublings. Forty doublings in the tumor system, you die. So, even finding a 1 centimeter tumor, you are 75 percent of the way through the natural history of that disease.

Mammograms, it is estimated, probably can detect a tumor 2 years before we can feel it. There is probably a narrow window where we can find cancer before it has spread. No question mammograms will find tumors earlier and smaller.

There are biologic other phenomena called lead time bias, length bias, symptom bias. It's not a simple thing. Knowing about something earlier doesn't necessarily mean you survive longer. It might not affect the natural history. But there is no question that clinical

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trials in this country have affected the outcome of breast cancer in the world.

Small cancer is not necessarily early.

Finally, we are seeing many, many women with cancers at a much younger age. We are seeing women just out of their teens with breast cancers. Cancer is an epidemic.

My plea is to get ahead with randomized clinical trials of a scientific outcome.

Thank you very much for allowing me the opportunity and privilege of testifying.

[The prepared statement of Dr. Lerner follows:]

PREPARED STATEMENT OF HARVEY J. LERNER, M.D., CHAIRMAN, DEPARTMENT OF SURGERY, THE GERMANTOWN HOSPITAL AND MEDICAL CENTER, PHILADELPHIA, PA

It is estimated that one out of every three American children born in the United States in 1985 will develop an invasive cancer at some time during their lifetime. For the past several decades, breast cancer has been the most common cancer which women have developed and has been the leading cause of death in women. For centuries some form of surgery has been the only therapy. Surgery could have been local excision. During the past 100 years, larger and more disfiguring surgical procedures have been developed. In 1894 Halsted had published his paper describing a classical radical mastectomy which removed the breast, the skin, the nipple, and the muscles of the chest wall which consisted of the pectoralis major and minor and performed an axillary node dissection. At the turn of century Handley reported on the use of a modified radical mastectomy which removed the breast, the skin, the nipple, the fascia from the pectoralis major and did an axillary node dissection. In 1952, Urban reported on an extended radical mastectomy which removed the breast, the muscles of the chest wall, the axillary nodes and also removed the internal mammary nodes which are the nodes medial to the breast and located between the ribs.

During the same year Dahl-Iversen, in 1951, reported on a superradical mastectomy which removed the breast, the muscles, the axillary nodes, and internal mammary nodes. It could possibly remove the chest wall full thickness and a graft of some sort would be placed in the defect and would also perform a supraclavicular node dissection. At no point in history had a clinical trial been performed to determine the value of any of these surgical precedures. Bloom had reported a series of patients who were untreated and demonstrated a ten year survival rate of 5% for untreated breast cancer. A TNM system of classification has been devised in order to help standardize staging in an effort to compare the value of various treatments reported by different investigators. The TNM system consisted of T, tumor size; N, lymph node status; and M, distant metastases. The various combinations of this TNM classification were then placed into a staging system: Stage I disease, which is essentially a negative node patient; Stage II, which is a very common form of cancer and is generally considered to have positive lymph node metastases; Stage III, which is locally advanced; and Stage IV which is distant metastases. The National Surgical Adjuvant Breast Project was the first major cooperative group clinical trial to treat and help to understand the pathophysiology of breast cancer. The NSABP demonstrated that patients who had negative lymph nodes had a 79% survival rate; one to three positive nodes was 62%; and four or more positive nodes was 30%. However, the disease free survival was quite different; for instance, four or more positive nodes at five years had less than 20% disease free survival. The ten year survival rate reported by the NSABP was 65% for negative nodes, 38% for 1 of 3 nodes and 13% for 4 more nodes. The most meaningful method of comparing one trial to another was comparing treatment by TNM staging, comparing one stage of treatment to another. The Italian National Cancer Institute at Milan recently reported a randomized prospective clinical trial comparing a standard Halsted radical mastectomy to that of an extended radical mastectomy. There was no difference in survival at five or ten years. Survival in Italian women for negative and positive nodes was essentially identical to American women. An interesting finding was if the axillary nodes were negative but the internal mammary nodes were positive, only 40% were disease free at ten years. If the internal mammary nodes and the axillary nodes were both positive, then the disease free survival at ten years was approximately 3%. This was in clinically operable breast cancer. Another randomized trial performed by the National Surgical Adjuvant Breast Project was that of randomized

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oophorectomy (removal of the ovaries) for Stage I and Stage II breast cancers. This trial demonstrated no significant difference in recurrence or survival. The National Surgical Adjuvant Breast Project also did a randomized trial to evaluate the worth of post-operative radiation therapy following a radical mastectomy. This trial did not demonstrate any significant increase in survival with the use of post-operative radiation. The Wallgren trial from Sweden was performed recently in an effort to demonstrate the possible value of pre-operative radiation therapy compared to post-operative radiation therapy or no post-operative radiation therapy; and at ten years, there was no significant difference in survival. After World War II, McWhirter did a trial in Europe which consisted of just performing a total mastectomy (simple mastectomy) with no removal of the axillary nodes; and the patients received post-operative radiation therapy. It was not a randomized trial and compared results to prior historic results. Essentially, he reported no difference in survival when one underwent a total mastectomy with radiation therapy or a prior radical mastectomy. This was not a scientific trial and was not generally well accepted. Other trials then came about in Europe comparing prospectively a radical mastectomy versus a total mastectomy plus radiation therapy. These intial trials indicated no difference in survival.

In the United States, the National Surgical Adjuvant Breast Project took the lead and performed a historic trial in which over 1,500 women were randomized. Women with clinically negative nodes, were randomized to: 1. a standard radical mastectomy which removed the axillary nodes; 2. A total mastectomy with radiation therapy; the radiation therapy treated the axillary nodes, the supraclavicular nodes and the internal mammary nodes; 3. A total mastectomy with no therapy directed at any other regional lymph node groups. At ten years, there was no difference in any of the three treatment groups in survival or failure rates. In clinically negative mode women for all three groups the five year survival rate was approximately 75%; and the ten year survival rate was approximately 59%. However, the disease free survival for these three groups was approximately 60% at five years and approximately 47% at ten years. Women who had clinically positive nodes, were treated by one of two treatments: (1) a radical mastectomy with removal of the axillary nodes, or (2) a total mastectomy with radiation therapy to all three groups of regional nodes. Again, at ten years, there was no difference in failure rates nor any difference in survival rates. For women with clinically positive nodes, the five year survival rate was approximately 60% and the ten year survival rate 38%. However, disease free survival for this group was approximately 42% at five years and 27% at ten years. The NSABP demonstrated that the error between clinical staging and pathologic staging is between 25 and 40%. Another important modern trial was that of the King's Cambridge Trial for Stage I and Stage II breast cancers. All patients received a total mastectomy, and were then randomized. One half of the patients received post-operative radiation therapy and the other group received no additional threapy. The group which received no additional therapy was referred to as the "Watch Group"; and if there was local axillary node progression, they then received radiation therapy to the lymph node bearing area. This trial contained over 2,200 patients; and at ten years, there was no significant difference in survival.

In Europe, more recently, several small trials were reported using local excision of the breast tumor followed by post-operative radiation. These trials implied good cosmetic results with acceptable survival rate when compared to mastectomy. The Guys Hospital trial from London compared a prospective randomized trial of 350 patients comparing a partial mastectomy versus a radical mastectomy; both groups receiving a small amount of radiation therapy to the axillary area; and the group having a partial mastectomy received a small amount of radiation therapy to the breast. For both groups, a local recurrence rate in the breast was quite small; and the overall survival, both for Stage I and Stage II, was quite acceptable. Subsequent to this, the Italian National Cancer Institute (Veroinesi) did a trial for clinical Stage I tumors less than 2 cm. with clinically negative nodes. The trial was randomized comparing a radical mastectomy to removing a quadrant of the breast with an axillary node dissection and giving a significant amount of radiation (6,000 rads) to the breast. There was no significant difference in recurrence or survival in either arm, indicating that less than a mastectomy in a randomized trial was quite satisfactory. The National Surgical Adjuvant Breast Project again took the lead; and approximately ten years ago instituted Protecol B06 which was a trail comparing 1. a total masectomy with an axillary node dissection to 2. a segmental mastectomy (lumpectomy) plus an axillary node dissection plus radiation therapy to the breast. The NSABP has always instituted quality control; and the removal of the lump from the breast required that the pathologist demonstrate that there was no evidence of tumor at the edge of the resected specimen. The exciting five year results have re-

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cently been reported and survival for all three arms is identical. However, a failure rate in the breast if the breast did not recive radiation was in the range of 30% at five years. If the breast received post-operative radiation, the recurrence rate was approximately 7% which compared favorably with the local recurrence rate in the skin following a mastectomy. Coppin has reported that approximately 90% of patients report to the physician with regional cancer (breast and/or nodes); and that 80% of the total will die from breast cancer at some time. Even at 15 and 20 years following a mastectomy, the death rate for breast cancer is twenty fold greater than the death rate for the normal population with deaths from breast cancer continuing at 30 years. Several papers have reported that neither patient nor physician delay adversely affects outcome. The Cancer Society data indicates that deaths from breast cancer have essentially been a straight line from 1930 to 1980 despite bigger operations, antibiotics, blood transfusions intensive care units, etc. etc.

One can compare size of a tumor with relation to lymph nodes and give some prognosis as to outcome. The NSABP has demonstrated when a tumor is 1 mm. to 9 mm. 22% of the patients already have axillary node metastases and 44% of these patients already have four or more nodes involved in tumor. Walter Bauer has reported that 90% of lymph node metastases have already occurred by the time the primary tumor is 6 mm. in size. Another important prognostic indicator is estrogen and progesterone receptor status with particular reference to menopausal status. The Milan data indicated for node negative women following mastectomy and who are ER negative, the five year survival is approximately 39% compared to the same group who are ER positive in which the five year survival data is approximately 85%. It is important to understand the natural history of any tumor system. In general, most cancers are long term processes. It takes a long period of time to induce a cancer. Once a cancer is induced, it remains in-Situ for a significant period of time (many years). An in-Situ cancer is a noninvasive cancer. Some of these cancers may even spontaneously disappear. However, once the cancer becomes invasive it may disseminate almost as rapidly as it invades. In an effort to understand tumor growth the following is an example. It is estimated that the average breast cancer cell is approximately 10 microns. It takes 20 doublings to go from one cell to 1 mm. in size; 1 mm. being approximately the size of a dot of a lead pencil. It takes only another seven doublings to 30 doublings which is 1 cm. in size. Ten doublings is a thousand cells; 20 doublings is a million cells; 30 doublings is a billion cells. The average breast cancer in America is approximately 3 cm. which is 35 doublings. Death usually occurs in most tumor systems at 40 doublings. The doublings range for cancer can range very briefly from two to three days to a prolonged period of time of several hundred days. The average doubling for a breast cancer is somewhere around 60 to 100 days. For example, at a hundred day doubling time, it takes approximately six to eight years to reach 1 cm. in size. If one is fortunate, the mammogram may pick up a lesion or an area of suspicious calcification at approximately 1 mm. in size. It is estimated that microcalcifications can be recognized as early as 20 doublings and a possible mass visualized at 22 or 23 doublings. It should also be stated that somewhere between 15 and 20% of breast cancers will not be recognized or visible by mammogram. It is also estimated that a mammogram may detect a breast cancer approximately two years before it is palpable. It is generally accepted that tumor cells can be found in the circulation after 20 doublings and that most metastases have occurred by the time the tumor has reached 30 doublings, 1 cm. in size.

It should be noted that there are several recognized statistical biases in biologic evaluation. These are lead time bias, length bias and symptoms bias. Finding a cancer earlier may give the appearance of increased survival but in reality it may not make any difference in the natural history of that tumor from onset to death. It should be emphasized that a small tumor is not necessarily an early tumor. It is without question, finding small tumors will give women many more treatment options with particular reference to having their breasts look almost identical after their cancer is treated. I personally would also like to stress and place strong emphasis upon the fact that great strides have been made and will only continue to be made by participation in well-planned, randomized prospective clinical trials as outlined by the National Surgical Adjuvant Breast Project. A finding from the recent meeting in Washington of the Consensus Meeting regarding adjuvant chemotherapy for breast cancer absolutely came to the same conclusion regarding the treatment of women in clinical trials.

Ms. OAKAR. Thank you, Doctor. That was very interesting.

I have a few questions, but I will save them for the end. Our next witness is Ms. Diane Blum.

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Thank you, Diane, for being here. Diane is with Cancer Care.

STATEMENT OF DIANE BLUM

Ms. BLUM. Mr. Chairman and members of the subcommittee, thank you for the opportunity to be here today. My name is Diane Blum. I am director of social service at Cancer Care and the National Cancer Foundation in New York City. My experience with cancer patients spans 12 years at the Farber Cancer Institute at Harvard Medical School, with Memorial Sloan-Kettering in New York, and now as director of social service at Cancer Care.

Cancer Care is a voluntary social agency that was founded in 1944 to help cancer patients and their families cope with the psychological, social, and financial impact of cancer. During the past 41 years, we have helped over 170,000 cancer patients and their families deal with the stresses of this disease.

Over 20 percent of our patients are women with breast cancer, many of them in the latter stages of the disease. Many of these women are coping with the disease that has limited their functioning over a period of years and has depleted the energy and resources of their families. One such patient, Mrs. U, is a 49-year-old mother of four who was diagnosed with stage 2 breast cancer around 3 years ago. Her mother had died from breast cancer at age 60. However, Mrs. U, even though she had this high risk status, didn't have any regular medical followup. As she explained, she had four children, ages 10 to 19, whose medical problems needed priority as the family tried to cope with their medical bills. Mrs. U doesn't work outside of her home. Her husband is employed as a factory worker with good inpatient medical insurance but inadequate outpatient coverage. She discovered her breast lump accidentally, had a mastectomy and node dissection, with 14 positive nodes indicating advanced disease. She was treated with chemotherapy but unfortunately relapsed only a year after the completion of the chemotherapy, with metastatic disease to her bones.

Mrs. U came to my agency, Cancer Care, to seek help with her adolescent children around the issue of her cancer, and financial assistance to provide help at home as she was unable to carry out her usual responsibilities. We have been working with Mrs. U for about 1 year now. She has widely metastatic disease and is confined to her home. Her family has incurred large medical bills. Her children and her husband have experienced enormous stress, and Mrs. U frequently says that she wishes she could die quickly so that her family could resume some semblance of normal life.

Mrs. U would have benefited from regular mammograms and from routine breast self-examination. Hopefully, her breast cancer could have been diagnosed earlier with a better prognosis. However, she was uninformed of any of the steps she could take to diagnose breast cancer earlier and certainly had no knowledge of mammography as a resource for herself. Unfortunately, her situation is typical of many. The devastating impact of this illness on patients and families could be prevented by greater public awareness of the importance of early detection of breast cancer and the development of resources for early detection. National Breast Cancer Awareness Week is a first step in meeting this need.

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Cancer Care is honored to have been asked by Stuart Pharmaceuticals to sponsor this week, and a yearlong program to educate women about the importance of early detection of breast cancer. Women are particularly fearful of breast cancer because of their dread of mastectomy. There are many women who practice health prevention behaviors such as stopping smoking, regular exercise, and healthy diets, but don't include breast cancer detection in their concerns. To them, detection techniques symbolize their fear of mastectomy and death from cancer.

Clearly, what we need to do is educate women. This is the purpose of the Stuart program. We want to inform women all over the United States that early detection can lead to more treatment options and to better prognosis. As you learned earlier, this program is under the leadership of Susan Ford Vance, who with her mother, Betty Ford, has made public service announcements stressing the importance of early detection. These public service announcements will be seen by 80 million people over this week and several weeks to come. The organizers of the program have worked with TV, radio, and the print media to announce National Breast Cancer Awareness Week and to let women all over the country know of the availability of public services that will teach them how to do breast self-examination and will educate them about breast cancer. Eighteen national publications have carried this story. Millions of other people will hear about it from TV, radio, and their local newspapers.

This week alone, there are 65 workshops in 25 different States to teach women how to do breast self-examination and to give them the facts about breast cancer to try and allay their fears. Stuart Pharmaceuticals has printed 4 million brochures about breast cancer that are being distributed to physicians and pharmacies throughout the country.

A very exciting part of this program is the informal network which has developed throughout the United States as professional and lay groups step forward to contribute their services. There are dozens of other programs this week going on in a total of 33 States, which range from displays in a shopping plaza in Indiana, to a mobile health service outside of Seattle that this week is doing free mammograms. The Cancer Center of the Southwest in Oklahoma City has invited 600 women tonight to have dinner with the Governor's wife to learn about the importance of early detection. They planned this program called A Moment for Myself particularly to coincide with National Breast Cancer Awareness Week. The Y-Me Program in Chicago on their own organized 21 different programs this week in Chicago, including Spanish programs, to educate women about the importance of early detection.

Our experience with developing this program has shown that there are individuals and agencies throughout the United States that are committed to the early detection of breast cancer. These people have been educating women on their own and have used the momentum of National Breast Cancer Awareness Week to further develop and expand their programs. However, education is only the first step. This becomes very clear as many women over the past couple of weeks have called Cancer Care and said they have heard about National Breast Cancer Awareness Week and they want to

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have a mammogram. They raise issues of cost, insurance reimbursement, no Medicare coverage, the necessity to see a physician who will schedule the mammogram for them, as deterrents for them and ask what can they do. In New York City we are fortunate to have several clinics such as Dr. Strax', which offer low-cost, accessible mammograms. However, the need is far greater than the services offered in New York and throughout the country.

I would ask the Congress to ensure that women of all ages be educated about the benefits of early detection of breast cancer and have access to low-cost, available, and safe mammography. Education is the first step in the process of breast cancer screening. This is what we are trying to do this week with the breast cancer awareness program. However, unless women are able to follow up on their newly acquired knowledge and obtain mammography easily, the goals of the program cannot be fully met.

Thank you very much.

[Material submitted by Ms. Blum follows:]

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Breast Cancer
Your Best Protection...
Early Detection

The National Cancer Foundation, Cancer Care, Inc

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Like most American women, you are probably aware of breast cancer. Yet most women are reluctant to take a few minutes each month to do breast self-examination. The reason is fear: fear of finding a lump and fear of losing a breast. Breast cancer is perhaps one of the greatest fears women have about their health.

Yet this fear can be your worst enemy if it prevents you from performing simple breast examinations each month and visiting your physician for regular checkups. **Early detection is the best weapon women have against breast cancer.**

The Facts

Your chances of developing breast cancer are one in 11.

About 115,000 new cases of breast cancer are diagnosed each year. Breast cancer is one of the leading causes of death from cancer, but it doesn't have to be, because it's one of the easiest to detect. Surprisingly, 9 out of 10 breast cancers are found by women themselves, **mostly by accident!**

If breast cancer is detected early enough, there may be no need for mastectomy. Yet only 25% of women perform deliberate, monthly self-examinations. Breast self-examination, combined with regular physician checkups and mammography (a safe, low-dose x-ray technique that can show tumors in the breast before they can be felt) are the most important things a woman can do to protect herself.

In reality, the *future* for those who do develop breast cancer has never been more promising. In less than a decade, the five-year survival rate* for women whose cancer is found early has risen to 87% because of advances in early detection, improved surgical procedures, hormonal therapy, and chemotherapy.

If you perform a self-examination and find a lump, **don't panic!** The vast majority of lumps are not cancer, but only your doctor can make that determination.

Breast Self-Examination and Medical Examination

Breast self-examinations should be performed after each menstrual period. Before your period many of the normal lumps in your breast may swell and become hard. If you no longer menstruate, do the exam on the first day of

*Percentage of women whose illness has not recurred five years after completion of treatment.

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each month. It is important that an examination by a physician be performed at least every three years from age 20 to 40, and every year thereafter. Your doctor is trained to distinguish what may be a problem tumor from a normal lump.

Low-Dose Mammography

The mammogram, an x-ray of the breast, produces a sharp, detailed picture that can reveal small tumors accurately up to two years before they can be felt. This makes mammography a most valuable tool. Mammography now uses very small amounts of radiation making the test a safe one.

The American Cancer Society recommends that women between the ages of 35 and 40 have a baseline mammogram done for later comparison. Women 40 to 49 are urged to have a mammogram every year or two, depending on their relative risk of developing the disease. Those over 50 should have a mammogram every year.

Current Treatments

No single treatment is right for all breast cancer patients. Several methods may be used and treatment varies according to age, overall health, patient and physician preference, the kind and extent of cancer, and other considerations.

Surgery

Several types of surgical procedures are commonly used to treat breast cancer:

- **Modified Radical Mastectomy:** This involves removal of the breast and lymph nodes in the armpit.
- **Simple Mastectomy:** Only the breast is removed. Patients with certain types of tumors and elderly patients often undergo this procedure.
- **Lumpectomy and Radiation:** Only the tumor and some surrounding tissue are removed. Frequently, the lymph nodes are removed separately for examination. After surgery, radiation therapy to the specific area is generally required.

Additional Treatments

Additional treatment may be required after surgery to prevent growth of or to destroy any remaining cancer cells. The most common therapies include: **hormonal therapy,** a drug therapy used to prevent growth of hormone-dependent cancers; **chemotherapy,** treatment with cell-destroying drugs; and **radiation therapy,** generally applied after surgery to the area from which the tumor was removed.

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Commonly Asked Questions About Breast Cancer

What Is Breast Cancer?
Breast cancer is a disease caused by uncontrolled growth of abnormal cells in the tissue of the breast.

Is Breast Cancer Curable?
Breast cancer responds well to therapy when detected early. If it is treated before cancer cells have spread, the chance of the disease *not* recurring is 87% or higher.

Can Breast Cancer Be Prevented?
Breast cancer cannot be prevented, but its spread can be controlled through early detection techniques such as regular breast self-examination, regular physician examinations, and low-dose mammography.

What Causes Breast Cancer?
The cause of breast cancer is not yet known. Researchers are investigating the role of viruses and diet in the development of the disease.

Can an Injury to the Breast Cause Cancer?
No, but it can make an existing breast cancer more apparent.

Do Birth Control Pills Increase my Chances for Developing Breast Cancer?
No. Medical studies of women who have had breast cancer fail to indicate that the pill has any effect on development of the disease.

How Can I Tell if I Am at Risk for Developing Breast Cancer?
Some women may be at higher risk than the general population for developing breast cancer. They include women who have several of the following characteristics:

- Over 50 years of age
- With a family history of breast disease
- Who have never had children
- Who had their first child after 30
- With a family history of benign breast disease
- Who began menstruating before age 12
- Who began menopause after age 50
- More than 10 percent overweight

Even if you don't fit into one of these categories, you should take special care to perform monthly self-examinations, and have low-dose mammography as appropriate.

This educational program is sponsored by the National Cancer Foundation, made possible by a grant from Stuart Pharmaceuticals, Division of ICI Americas Inc.

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Ms. OAKAR. Thank you very much, Ms. Blum. You are doing a great job as well.

Our next witness is Mrs. Rose Kushner, author of "Alternatives." Rose, thank you for being here.

STATEMENT OF ROSE KUSHNER

Mrs. KUSHNER. Congressman Pepper, Congresswomen Oakar and Bentley, distinguished members of the committee, and ladies and gentlemen, thank you for inviting me today to be a witness on behalf of breast cancer. I would also like to congratulate this committee for having a second, and repeat, performance of Breast Cancer Day on Capitol Hill. As you can see, it is needed.

In addition, Stuart Pharmaceuticals should be congratulated for sponsoring a National Breast Cancer Awareness Week. Stuart is obviously a company that is trying to put itself out of business, because it does make an anti-breast-cancer drug. By urging early detection of breast cancer, this is the ultimate of philanthropy.

My name is Rose Kushner. In 1974, I was treated for breast cancer. After writing an article about my difficulties in finding state-of-the-art diagnosis and treatment 11 years ago, I was asked to write a book about the disease. The need for information and help is still so great that its fifth edition has recently been published.

In 1975 I began the breast cancer——

Ms. OAKAR. Now, you'd better give us the name of your book.

Mrs. KUSHNER. "Alternatives," as you mentioned. I don't think it's modest to keep repeating it, but I'll do it.

In 1975, I began the Breast Cancer Advisory Center—the BCAC—to help women and men—one of every hundred breast cancers falls into the breast of a man—who need personalized help about their individual problems. This help has ranged all the way from telling teenagers that going braless will not cause breast cancer to discussing continuing-care and hospice, at the other end of the spectrum.

I was appointed to a 6-year term as a member of the National Cancer Advisory Board, the NCAB, by President Carter in 1980. Because of my continuing involvement with problems related to breast cancer, I was privileged to be invited to testify before this select committee on June 28, 1984, the first Breast Cancer Day on Capitol Hill. The comments I made last year about my personal experiences are already in the record of that hearing and do not need to be repeated now. But I would like to point out that none of the issues I discussed has gotten any congressional attention in the 16 months that have since gone by.

Before beginning, since I note that there is a place on the agenda for an official, quote, Federal response, end quote, I would like to emphasize that I am testifying before this committee as an individual. I am testifying as the executive director of the Breast Cancer Advisory Center and not as a representative of the National Cancer Advisory Board. The opinions I will give are my own and do not represent those of the NCAB, the National Cancer Institute, or the Federal Government.

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However, I am submitting a resolution that was passed unanimously by the NCAB at a public meeting on Monday, October 7, 1985:

The National Cancer Advisory Board strongly recommends that there be third-party reimbursement to include Titles 18 and 19 for scientifically established, cost-effective screening procedures such as Pap smears, hemocult testing, and mammography.

The previous witnesses have already said what I had planned to include in my testimony. In addition to their views, I would like to submit an article from the New York Times of July 20, 1976, by Dr. Lawrence Altman. It's headline is "Benefits Study for Cancer Test, Blue Cross Seeking Early Screening Contracts for U.S. Aided Research." This article, which has been submitted for the record, indicates that Blue Cross at that time seriously considered paying for screening—not diagnostic—mammography. The difference between the two has been stressed enough. Diagnostic mammography is covered. But that is done when a woman already has a symptom, and it's probably too late.

Screening mammography involves x raying women's healthy breasts to see if there is something occult, or hidden as was described earlier. This is what can be a life-saving procedure that is not being covered by Medicare, or by Blue Cross, or any other third-party carrier. The New York Times article points out that the Blue Cross officials contracted with the National Cancer Institute to find out if mammography was cost-effective, but apparently nothing happened. Blue Cross still does not cover breast screening by mammography.

I would also like to point out that H.R. 1402, introduced by Congresswoman Oakar on March 5, is very relevant to this hearing. Although I congratulate all the private agencies who are trying to do something, I do not think that screening should be dependent on private agencies. Annual screening by mammography, as Dr. Powers pointed out, will not only save women's lives but will also save the Federal Government money. The number of dollars Medicare would spend to screen women's breasts to detect curable cancer are far fewer than the $441.5 million paid in 1984 for hospital cost alone. This huge total does not include outpatient bills for doctors, drugs, and continuing care. The New York Time articles and all the other documents supporting this statement have been submitted for the record.

In addition, the second bill introduced by Ms. Oakar last March, H.R. 1579, requesting Federal legislation that would require every State to enact informed consent or "no-surprise" laws to inform women and men diagnosed to have breast cancer about viable treatment alternatives other than breast amputation, is also something that the Congress should act on.

By the way, I would like to stress the fact that in protocol B06 that Dr. Lerner described, the clinical trial showed that women who had lumpectomy without radiation lived just as long as the women who did have radiation. So, radiation may not always be required, and this option is not always pointed out to women. The two options, when they are given to women, are usually mastectomy or lumpectomy with radiation. Having a lumpectomy without radiation is also a viable alternative.

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I would like to spend the rest of my time responding to a question that has been raised several times: Are there actions that the Federal Government can do? Is the Federal Government responsible?

Yes, there certainly are actions that only the Federal Government and the Congress can take to protect women—and men—who have problems related to breast cancer. To save time, I will simply list them.

First of all, it is imperative that more money be appropriated for breast cancer research and treatment. While I know that the Congress has increased the National Cancer Institute's budget above the levels requested by the executive branch, the dollars are still not enough to do any of the things that have been described by the previous witnesses.

Second, on February 18, 1985, Senator Don Riegle, a Democrat from Michigan, introduced Senate bill 551, "To provide for the establishment of a registry to identify and aid individuals who have been exposed to the drug diethylstilbesterol [DES] and for other purposes." I am a DES mother. I think my cancer was caused by taking DES to prevent miscarriages. Fortunately, the baby I took it with did not live longer than 3 weeks. So, I am a DES mother with no DES offspring. I urge the Congress to support Senator Riegle in establishing this registry. Millions of women still do not know whether or not they took DES.

Ms. OAKAR. Rose, we have vote on the rule. What you are talking about is really important, because a lot of women took DES during pregnancy and got breast cancer. You have some other statistics and points that we want to hear. So, let us go vote. We will come back and resume with your other recommendations.

Mr. PEPPER. Madam Chairman, I may not be able to come back afterward, to my great regret, because of some other pressing matters.

Dr. Strax, I want to tell you how pleased I am that you are in Miami with your clinic now. I hope I might visit your clinic down there sometime soon. It is a commendable service that you are making available to the people of that area and apparently at a modest fee. I understood you said the detection could be for $25—$35.

Thirty-five, very well. So, I want to commend you on that. I am pleased that you are there. I am very much interested in what the Federal Government can do, as is Ms. Oakar, to try to protect the people of this country.

Mrs. KUSHNER. It's all there in the written testimony.

Mr. PEPPER. Yes, and we will be reading it, don't you forget it. Thank you.

Ms. OAKAR. We will be back.

Mr. PEPPER. Thank you very much for coming here today on this very, very vital matter.

Ms. OAKAR. Don't go unless you have a plane to catch, because I will be back to complete the hearing.

We also are going to hear from the Federal Government, the administration also. We will be right back.

[Recess.]

Ms. OAKAR [acting Chair]. The subcommittee will resume.

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Rose, you were just telling us about DES. Every person that I know that ever took that has breast cancer, and that's really true, including members of my own family. You were just talking about that. We should probably have a special hearing on that.

Mrs. KUSHNER. Within the last year, there were data published by the National Cancer Institute. There are three institutions following the DES offspring, because DES sons, as well as daughters, are starting to have troubles. I think the institutions are Mayo, Harvard, and Chicago Lying-In. While they were following the offspring, they also followed the DES mothers, and they are finding that DES mothers have half again as much breast cancer as would normally be expected. Again, it is a bill sponsored by Senator Don Riegle: S. 551, introduced on February 18, 1985.

The third Action needed by cancer patients from Congress concerns discrimination. On July 23, 1985, Representative Mario Biaggi, a Democrat from New York, introduced H.R. 1294, a bill to "outlaw employment-based discrimination against persons with a cancer history."

There is documentation about leakages from insurance companies concerning people's medical records. Some of these are accompanying my written statement. I would like to point out to the members of this committee that the laws the Congress has enacted to protect Americans' medical privacy are being violated every day by these illegal leakages of privileged information to employers, to employment agencies, to credit agencies, and to other insurance companies. This adds financial troubles to the life-threatening problems that all breast cancer patients are already facing.

Fourth is Public Law 97-35, the "Consumer-Patient Radiation Health and Safety Act" that was enacted on August 13, 1981. It is not protecting Americans from potentially hazardous radiation. I want to stress that good mammography is not included in this fear of hazardous radiation caveat. However, there are documents in my written testimony that discuss the dangerous radiation that is still around in diagnostic and therapeutic radiation equipment, but not good mammography equipment. But I am sure that everybody on this panel will agree that there is still not always good mammography equipment in the United States. Women should be alerted about that and should go to a good institution for mammography.

I urge members of this subcommittee to do whatever is necessary to see to it that Public Law 97-35 is enforced. Since this bill, H.R. 1402, is one that involves the use of medical radiation, I think that such intervention would be appropriate by the members of this committee.

Five, breast reconstruction for women who had have mastectomies, as has been previously mentioned, has been recommended by physicians, surgeons, and all health agencies for both physical and psychological rehabilitation. Medicare, I am happy to say, was among the first third-party carriers to pay for reconstruction even though everyone is older than 65. And CHAMPUS, the Government insurance company that covers military dependents, has also agreed to pay for breast reconstruction. This is also in my written testimony. But many States still do not require third-party carriers to cover such rehabilitation procedures, and insurance companies

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can refuse—and they do refuse—reimbursement on the grounds that reconstruction is merely "cosmetic."

These issues and others are summarized in an article that I wrote recently called "Lobbying for Better Breast Care." It is in Women's Health magazine, the issue for winter, 1985. A copy of the article is with my statement.

As you have heard and will read, I feel strongly that breast cancer is not only a potentially fatal disease but is also a serious political issue. This is the thrust of my testimony before this committee today and of my writing and speaking to women throughout the United States. We compose more than one-half of our country's 1985 voting population, and we will be demanding that our elected Members of Congress do something to help us.

Thank you for giving me the opportunity to speak.

[The prepared statement of Mrs. Kushner follows:]

TESTIMONY OF ROSE KUSHNER, EXECUTIVE DIRECTOR, BREAST CANCER ADVISORY CENTER, KENSINGTON, MD, MEMBER: NATIONAL CANCER ADVISORY BOARD

Congressman Pepper, Distinguished Member of the Committee, Ladies and Gentlemen:

My name is Rose Kushner. In 1974, I was treated for breast cancer, and—after writing an article about my difficulties in finding state-of-the-art diagnosis and treatment eleven years ago—I was asked to write a book about the disease. The need for information and help is so great that its fifth edition has recently been published.

In 1975, I began the Breast Cancer Advisory Center (BCAC) to help women—and men—who needed more information about their individual problems breast cancer than they were able to obtain from their doctors or from my books.

From 1975 until 1982, the BCAC had a "hotline' as well as a mail service, and its telephone number and address received a great deal of publicity. By now the Center has been contacted by about 30,000 women, and men, who have, or are worried about having, breast cancer.

I was appointed to a six-year term as to the National Cancer Advisory Board (NCAB) by President Jimmy Carter in 1980, and—because of my involvement with problems related to breast cancer—I was privileged to be invited to testify before this Select Committee on June 28, 1984. The comments I made last year are already in the record of that hearing and do not need to be repeated, but I would like to point out that none of the issues I discussed has gotten any Congressional attention in the sixteen months that have since gone by.

Before beginning, I would like to emphasize that I am testifying before this Subcommittee as an individual and not as a representative of the NCAB: my opinions are my own and do not reflect those of the Board or of the National Cancer Institute (NCI). However, I am submitting a resolution that was passed unanimously by the NCAB at a public meeting on Monday, October 7, 1985.

"The National Cancer Advisory Board strongly recommends that there be third party reimbursement, to include Title XVIII and XIX, for scientifically established/cost effective screening procedures such as PAP smears, hemocult testing and mammography."

I understand that a relevant bill—H.R. 1402—was introduced by Congresswoman Oakar on March 5, 1985, and I urge members of this Committee to support this important effort. Annual screening by mammography would not only save women's lives but would also save the federal government money: the dollars Medicare would spend to screen women's breasts to detect curable cancer are far fewer than the millions paid in 1984 for doctors, hospitals, X-rays and drugs. Documents supporting this statement have baeen submitted for the record.

In addition, Ms. Oakar introduced another bill last March—H.R. 1579—requesting federal legislation that would require every state to enact informed consent or "no surprise" laws to inform women, and men, diagnosed to have breast cancer about viable treatment alternatives other than breast amputation. Massachusetts California, Hawaii, New York, Florida and Pennsylvania already have laws regarding breast cancer, and legislation is pending in many other state legislatures. However, there is little uniformity in the various Acts' requirements, and there is a need for the equal protection of women under the law. Such protection can only be guaran-

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teed by the Congress, and I urge the members of this Committee to support Ms. Oakar in this effort as well.

There are other actions that only the Congress can take to protect women, and men, who have problems related to breast cancer. To save time, I will simply list them:

1. On February 18, 1985, Senator Don Riegle. (D-MI) introduced S. 551 "To provide for the establishment of a registry to identify and aid individuals who have been exposed to the drug diethylstilbestrol (DES), and for other purposes." Again, information supporting this bill accompany my written statement.

2. On July 23, 1985, Rep. Mario Biaggi (D-NY) introduced H.R. 1294, a bill to "outlaw employment-based discrimination against persons with a cancer history."

As the accompanying documents will show Members of this Subcommittee, the laws that were enacted by the Congress to protect Americans' medical privacy are being violated every day. Illegal leakage of privileged information to employers and to employment agencies adds financial troubles to the life-threatening problems cancer patients must face.

3. Public Law 97-35—the Consumer-Patient Radiation Health and Safety Act—that was enacted on August 13, 1981 is not protecting Americans from potentially hazardous radiation. I urge Members of this Subcommittee to do whatever is necessary to see to it that this law is enforced. Since H.R. 1402 is a bill that involves the use of medical radiation, such intervention would, I think, be appropriate.

4. Breast reconstruction for women who have had mastectomies because of cancer is now recommended by physicians, surgeons and all health agencies for both physical and psychological rehabilitation. Nonetheless, many states still do not require third-party-carriers to cover such procedures, and insurance companies can refuse reimbursement on the grounds that reconstruction is merely "cosmetic."

Three of these issues are summarized in an article, "Lobbying for Better Breast Cares," that I recently wrote for Women's Health Magazine (Winter, 1986). A copy of this article accompanies this written statement.

As you can hear, and will read, I feel strongly that breast cancer is not only a potentially fatal medical disease but is also a political issue. This is the thrust of my testimony before this Subcommittee today and of my writing and speaking to women throughout the United States. We are more than half of our country's 1985 population, and we will be demanding that our members of Congress do something to help us.

Thank you. I will be delighted to answer any questions you may have.

[The articles follow:]

[From Women's Health, Winter 1986]

Lobbying for Better Breast Care

(By Rose Kushner)

Breast care could be as hot a political issue in 1986 as the Equal Rights Amendment—if women learn where the legislative battles are and join forces to help win them.

Here are four of the key issues, with positive-action steps we can take to make the politics of breast care work for us.

REGULATION OF MAMMOGRAPHY EQUIPMENT

While the U.S. Bureau of Standards inspects scales in bakeries and butcher shops to be sure customers are not overcharged for their baloney, there is no government agency that inspects x-ray equipment in hospitals and breast-cancer clinics to ensure that we are not over exposed to cancer-causing radiation!

Since 1968, the federal government has had a bureau (now called the Center for Medical Devices and Radiological Health) within the Department of Health and Human Services that is charged with the formidable job of monitoring all equipment in the country that uses radiation. Only the construction and installation of the hardware is regulated, however, not the way it is used.

What does this mean for women?

There are no federally enforced minimum standards regarding the training or experience of the people who push the buttons of potentially hazardous mammorgraphs. (It is sometimes more difficult to become a shampoo girl in a hair salon than it is to become an x-ray technican!)

While federal inspectors may inspect mammography equipment when it is in the factory and in offices and clinics immediately after it is installed, they can do noth-

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ing about maintenance and calibration of the machinery or the quality of the film and chemicals.

There is no legal requirement that women's breasts be x-rayed by dedicated mammography equipment as opposed to the machines used to find broken bones.

Recommended action: Write or telegraph your congressional delegations to revive the work of former Senator Jennings Randolph (D-W.Va.), who fought for federal standards to regulate all aspects of medical radiation. Since he left the Senate, in 1983, no one has taken over his crusade.

INFORMED CONSENT IN BREAST-CANCER TREATMENT

On March 19, 1985, Congresswoman Mary Rose Oakar (D-Ohio), introduced bill H.R. 1579—the "breast-cancer treatment informed-consent act"—into the House of Representatives. This bill was also introduced in 1984, but it never reached the floor for a vote, and this must not happen again. If passed and signed by the President H.R. 1579 will require every state to enact "no surprise" legislation or be punished by losing federal money now received under the terms of three Social Security and Public Health Acts.

This means that, except for women who sign a statement before surgical breast biopsy that they don't want a "two-stage procedure," all will awaken from anesthesia with two intact breasts, giving them time to get second opinions.

How did unnecessary breast surgery get to the hallowed halls of Congress?

Woman power.

The standing room only crowd in Room 2212 of the Rayburn House Building in Washington was hushed on June 28, 1984. Members of the House Select Committee on Aging listened quietly as Carolyn Alford, a Virginia mother of four, testified on behalf of a national "no surprise" act to protect women's breasts.

She was only 31 years old in 1974 when she found the small lump in her left breast. Certain that it was "harmless," her doctor recommended a surgical biopsy under general anesthetic and promised her she would be home within a day or two. Mrs. Alford, however, refused to sign hospital papers that would permit a mastectomy if cancer was discovered while she was unconscious on the operating table. Hours later, she awoke in agony to discover that her breast, pectoral muscles, a section of her chest wall and the lymph nodes in her left axilla had been cut away from her body.

In a "30-second decision," her young and terrified husband signed the consent form, because the surgeon told him she would be dead in six months unless he authorized an immediate radical mastectomy.

Almost 10 years later, on August 12, 1983, Carolyn Alford had the satisfaction of being in a committee room of the Virginia Senate when the state's "breast-cancer informed-consent bill" was unanimously approved.

Versions of the "informed consent in breast-cancer treatment" are already on the law books of Massachusetts (1979), California (1980) and Hawaii (1983). About 22 other states have breast-cancer bill locked up in various committees and subcommittees of state legislatures by strong opposition from "organized medicine." To bypass the regional impasses, women can do more—more quickly—by directing their efforts to Washington.

Recommended actions: Write or telegraph your congressional delegations to support H.R. 1579 and write to President Reagan to sign it into law. (He still has time!) Contact every women's organization you know to urge support.

INSURANCE COVERAGE FOR BREAST-CANCER SCREENING

Along with the fear of needless surgery, the high cost of getting good breast care is of utmost concern to all women. Even though the American Cancer Society and the National Cancer Institute agree that every woman should be screened by mammograph each year after her 50th birthday, Medicare does not cover the examination. In the U.S. today, the cost of a private doctor's exam plus two x-rays of each breast ranges from $100 to $250.

H.R. Bill 1402, also introduced by Representative Oaker—and which also made its second Congressional debut last March—requires that Medicare pay for annual physical examinations and screenings of women's breasts.

Why do women need this law?

Alma Porter (not her real name), 67, had lost her mother, two sisters, five aunts and both grandmothers to breast cancer. She was sure she would also get the disease. But widowed and entirely dependent on her monthly Social Security checks, Mrs. Porter could not afford to be x-rayed every year. She did examine herself regularly, however, and found the tumor she expected when it was the size of a small

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pea. Unfortunately, it was too late to be an "early" breast cancer. Three malignant lymph nodes were found in Mrs. Porter's axilla, and her chances of living five years plummeted from 90 to 68 percent.

Mrs. Porter might have been spared from her grim prognosis if government supported Medicare followed government-supported NCI recommendations.

Recommended actions: Write or telegraph your congressional delegations to support H.R. 1402. Contact every women's organization you know to urge members of the American College of Radiology to reduce the cost of mammography for everyone. Remember: As Medicare goes, so goes Blue Cross-Blue Shield.

INSURANCE COVERAGE FOR RECONSTRUCTIVE SURGERY

We can also see to it that women who have had mastectomies are reimbursed for plastic surgery to replace their lost breasts. This is not always covered by medical insurance. Until 1974, insurance companies were not required to pay for external prostheses—the "falsies" breast-cancer patients use to fill the empty cups of their brassieres. Breast prostheses were considered "cosmetic," not rehabilitative devices!

Now women face the more modern and equally disturbing problem that many states consider reconstructive mammoplasty to be "cosmetic."

Happily, Medicare and the military hospitals cover breast reconstruction, but insurance requirements differ from state to state. Women in Massachusetts have successfully argued that testicular and penile implants have always been covered by insurance and that silicone breast should be covered in the same way. In California, all third-party carriers pay for the procedure for all insured residents, including indigent women protected by MediCal—regardless of their insurer for the original mastectomy. But some states still consider the procedure to be cosmetic, and reimbursement policies vary considerably.

Recommended action: Contact your state insurance commission to see what you can do to change insurance laws covering breast reconstruction in your area of the country.

Women accomplished miracles fighting against sex discrimination in hiring, equal pay for equal work and reproductive freedom by using the "system." As a result of women's political clout as 51.3 percent of the U.S. population, Sandra Day O'Connor is sitting on the Supreme Court, and Geraldine Ferraro ran as a candidate for Vice President. Getting better breast care is as important as these other feminine issues, and old-fashioned, ward-heeling politics can accomplish miracles—if women do something about it.

[From the New York Times, July 20, 1976]

BENEFITS STUDIED FOR CANCER TESTS

(By Lawrence K. Altman)

The Blue Cross Association said yesterday that the "recent sharply rising cancer death rate" in this country and rising costs of health care had spurred it to take a first step toward providing coverage for screening tests to diagnose malignant tumors at an earlier stage among its nearly 90 million subscribers.

Blue Cross officials said they had contracted with the National Cancer Institute, a Federal agency, to undertake a study, covering several years, of the various factors that would be involved in offering such a screening program as a prepaid health care benefit.

The program is aimed at detecting more cancers in the silent phase, before they have produced symptoms. Cancer is the country's second leading cause of death behind heart disease, and Blue Cross officials said they believed that many lives could be extended by earlier detection of cancer.

Walter J. McNerney, the Blue Cross Association president, said, "The study will determine whether the early detection and treatment of cancer would lead to improved survival rates and lower treatment costs and if so, whether it would be economically feasible to offer the new benefit on a nationwide scale."

In the first year of the study, which is scheduled to begin Aug. 1, Blue Cross and National Cancer Institute staff members will try to determine which types of cancer before symptoms develop. There are scores of different malignant tumors, all of which are categorized as cancer. Their detection depends on a wide variety of factors such as location in the body, age, sex and family history of cancer.

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Blue Cross officials said that the association did not know the specific types of screening tests that would prove worthwhile on a cost-effective basis for large population groups.

Among the ideas to be considered for study are the use of paramedical workers to do rectal examinations to detect bowl and prostrate cancers; mobile vans to bring x-ray machines to the work-site to do mammograms to detect breast cancer in women, and educational programs.

Blue Cross officials said they recognized that the program could lead to controversies over the use of nonphysicians, the choice of screening test, and choice of institution in a community where the tests would be offered.

AFTER DIAGNOSIS

Blue Cross currently covers the costs of treatment when cancer is diagnosed after suspicious symptoms have developed. Often such symptoms are discovered by the patient through such guidelines as the American Cancer Society's "seven early warnings signals," and through regular physical examinations in a doctor's offfice.

However, Blue Cross officials pointed out this self-discovery was not completely effective because cancer is often caught after it has already spread, reducing the patient's chances for survival.

Further, Mr. McNerney said, "The healthy person, free of any symptoms, often omits such routine cancer checkups because testing costs are not regularly covered by health insurance or prepayment programs."

One aim of the study is to determine whether death and sickness rates can be reduced when the financial barrier is removed and Blue Cross pays for testing before symptoms occur.

Most health officials have maintained that because of cancer's complexity, early detection through screening is becoming increasingly important as the best means to reduce cancer death rates. But, as Blue Cross said, the traditional models of screening have generated costs that are considered too high for coverage by health insurers and other third-party payers.

Accordingly, the study is aimed at seeking answers to such questions as the following:

How will the cost of treatment and the decrease in deaths from cancer for patients being screened compare with the costs of cancer treatment without early screening?

Will savings, if gained, balance the cost of administering the program and providing the benefit?

Which facilities should be used to make screening available to the large proportion of the population to be covered—hospital-based outpatient clinics, health maintenance organizations, industrial clinics, free-standing clinics, mobile or outreach clinics, or others?

What educational programs will be necessary to encourage the public to use early screening when cancer can be discovered soon enough to minimize early treatment?

Mr. PEPPER. Thank you very much, Rose.

The last witness, who we have already heard give a very interesting discussion of mammography, is Dr. Martin Thomas.

STATEMENT OF MARTIN THOMAS, M.D.

Dr. THOMAS. Madam Chairman, I am Dr. Martin A. Thomas. I am here to present the American College of Radiology's comments on mammography screening.

I am a fellow of the college and am a radiologist in private practice in Washington, DC. I am former chief of radiology at Columbia Hospital for Women and director of the Betty Ford Breast Diagnostic Center there. I have been active in mammography for the past 2½ decades.

Our testimony today is offered on behalf of the 17,000 radiologists and physicist members of the American College of Radiology. My full testimony consists of my prepared text and the college's policy statements on mammography and breast screening. I request that my text and statements be made part of the hearing record.

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The purpose of breast screening is to improve the survival of women by detecting breast cancer at an early stage. It is an attempt to detect unsuspected breast malignancy in ostensibly healthy women. The methods available are breast self-examination, clinical examination, and mammography. A mammogram can pick up a breast cancer at a nonpalpable stage, earlier than either the woman herself or the physician can detect it.

There is a parallel between screening mammography and the Pap smear. The mammographic procedure is highly safe, reliable and acceptable to the patient and can be definitive in a diagnosis of benign and malignant breast conditions. Mammography is capable of providing the diagnosis of carcinoma of the breast prior to its spreading outside the breast. Treatment applied at this stage can predictably produce a cure rate in excess of 90 percent.

The American College of Radiology recommends that at the age of 40 a woman receive baseline screening mammograms, and between the ages of 40 and 49 have a mammographic screening every year or two. The college recommends that at age 50 a woman have a mammographic screening annually. In September the council of the college concluded that the time has come to use mammography screening facilities as an initial step in breast cancer detection. The college encourages radiologists to set up screening facilities where women could go without the referral of a physician and in which costs would be kept to a minimum.

Radiologists are uniquely qualified to perform mammography. They possess the knowledge of x-ray equipment, receptor systems, radiation physics, and dosemetry, plus understanding the anatomy of the breast. Mammographic screening should be performed under the supervision of a radiologist with demonstrated experience and competence in mammography.

Radiologists completing their training in the past 10 years have received formal training in their residencies in mammography. Continuing education classes, like those offered by the college, provide training in new modalities and changing technologies. Radiologists not originally trained in these modalities or technologies are brought up to date very rapidly and thoroughly upon completion of these classes.

Let me reiterate at this time that it is the aim and purpose of the American College of Radiology to try to get a decline in that death rate that has remained flat over the last four decades by early detection of breast carcinoma through screening.

This concludes my oral statement. I would be happy to answer any questions.

[The prepared statement of Dr. Thomas along with the comments of the American College of Radiology follows:]

PREPARED STATEMENT OF DR. MARTIN A. THOMAS

Mr. Chairman, I am Dr. Martin A. Thomas. I am here to present the American College of Radiology's comments on mammography screening. I am a fellow of the College and am a radiologist in private practice in Washington, D. C. I am former chief of radiology at Columbia Hospital for Women here and have been active in mammography for the past two and a half decades.

Our testimony is offered on behalf of the 17,000 radiologist and physicist members of the American College of Radiology. Approximately 90 percent of the nation's medical specialists in the uses of radiation and other energy forms for diagnosis and

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treatment of disease are members of the College. Several hundred radiological physicists also are members.

My full testimony consists of my prepared text and the College's policy statements on mammography and breast screening. I request that my text and statements be made part of the hearing record.

The purpose of breast screening is to improve the survival of women by detecting breast cancer at an early stage. It is an attempt to detect unsuspected breast malignancy in ostensibly healthy women. The methods available are breast self-examination, clinical examination and mammography. A mammogram can pick up breast cancer at a non-palpable stage—earlier than either the woman herself or her physician can detect it. Therefore, the College believes that beginning at age 40, a mammographic screening should be a routine part of a clinical work-up for women. The College, the American Cancer Society and the National Cancer Institute endorsed annual mammographic screening for women over 50 after research proved the procedure contributed significantly to early detection.

There is a parallel between screening mammography and the Pap smear (Papanicolaou test), a detection test for uterine cancer introduced in the 1940s. When first introduced, there were some uncertainties about the test. However, today the Pap smear is widely-used, routine and inexpensive. Most importantly, since its introduction the death rate from uterine cancer has declined more than 70 percent.

MAMMOGRAPHY SCREENING

The mammographic procedure is highly safe, reliable and acceptable to the patient and can be definitive in a diagnosis of benign and malignant breast conditions. Mammography is capable of providing the diagnosis of carcinoma of the breast prior to its spreading outside the breast. Treatment applied at this stage can, predictably, produce a cure rate in excess of 90 percent.

The American College of Radiology recommends that at the age of 40, a woman receive base-line screening mammograms and between the ages of 40 to 49 have mammographic screening every year or two. The College recommends that at age 50 a woman have a mammographic screening every year. In September, the Council of the College concluded that the time has come to use mammography screening facilities as an initial step in breast cancer detection. The College encouraged radiologists to set up screening facilities where women could go without the referral of a physician and in which costs would be kept to a minimum.

In addition to the College, the American Cancer Society, American College of Obstetricians and Gynecologists and the American Academy of Family Physicians have issued similar guidelines for the use of mammography.

EXPERTISE

Radiologists are uniquely qualified to perform mammographic screening. They possess the expertise of imaging equipment, receptor systems, radiation physics, and dosimetry plus understanding of the anatomy of the breast. Mammographic screening should be performed under the supervision of a radiologist with demonstrated experience and competence in mammography. Expertise is needed in the actual imaging and interpreting the images.

Radiologists completing their training in the past 10 years have received formal training in mammography. Continuing education classes, like those offered by the College provide training in new modalities and changing technologies. Radiologists not originally trained in these modalities or technologies are brought up to speed very rapidly and thoroughly upon completion of these classes.

SUMMARY

Mammography screening has made a highly significant contribution in the detection of breast cancer in women. A mammogram performed under the supervision of an experienced radiologist coupled with a clinical examination has literally made the difference between life and death in thousands of women.

COMMENTS OF THE AMERICAN COLLEGE OF RADIOLOGY ON MAMMOGRAPHY SCREENING

The purposes of breast screening is to improve the survival of women by detecting breast cancer at an early stage. It is an attempt to detect unsuspected breast malignancy in ostensibly healthy women. The methods available are breast self examination, clinical examination and mammography. A mammogram can pick up breast cancer at a non-palpable stage—earlier than either the woman herself or her physi-

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cian can detect it. Therefore, the College believes that beginning at age 40, a mammographic screening should be a routine part of a clinical work-up for women. The College, The American Cancer Society and the National Cancer Institute endorsed annual mammographic screening for women over 50 after research proved the procedure contributed significantly to early detection.

There is a parallel between screening mammography and the Pap smear (Papanicolaou test), a detection test for uterine cancer introduced in the 1940s. When first introduced, there were some uncertainties about the test. However, today the Pap smear is widely-used, routine and inexpensive. Most importantly, since its introduction the death rate from uterine cancer has declined more than 70 percent.

MAMMOGRAPHY SCREENING

During 1984, approximately 115,000 American women—more than ever before—were faced with the diagnosis of breast cancer.[1] It is the most common cancer to strike American women, accounting for more than one-fourth of all women's cancers.[2] At the present rate, about 9 percent of all females in this country—approximately 1 of every 11 women—will develop breast cancer sometime during their life.[1]

The mamographic procedure is highly safe, reliable, and acceptable to the patient and can be definitive in a diagnosis of benign and malignant breast conditions. Mammography is capable of providing the diagnosis of carcinoma of the breast prior to its spreading outside the breast. Treatment applied at this stage can, predictably, produce a cure rate in excess of 90 percent.

The American College of Radiology recommends that at the age of 40, a woman receive base-line screening mammograms and between the ages of 40 to 49 have mammographic screening every year or two. The College recommends that at age 50 a women have a mammographic screening every year. In September, the Council of the College concluded that the time has come to use mammography screening facilities as an initial step in breast cancer detection. The College encouraged radiologists to set up screening facilities where women could go without the referral of a physician and in which costs would be kept to a minimum.

In addition to the College, the Americn Cancer Society, the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians have issued similar guidelines for the use of mammography.

COSTS

Historically, cost has been a significant deterrent to greater utilization of mammography as a screening examination. If screening is to benefit the population in general, mammography must be provided at the lowest possible cost. Charges for mammography should be realistic, reflecting true direct and indirect costs and a reasonable return for professional interpretation. Charges should reflect the service provided. Some facilities may elect to provide a screening examination at a different rate than that charged the referred symptomatic patient.

Health insurers as a rule do not cover routine, preventive-care exams like screening mammography. Many physicians see this as short-sighted realizing that it costs much less to catch and cure early disease than waiting until it is in its final stages. This is indeed the case with breast cancer. The average costs in treating breast cancer cases detected in an early stage is $18,000. The medical cost of breast cancer that is detected late—at the stage where simple surgery is not adequate—averages $60,000 because of more complex surgery, chemotherapy, radiation therapy and repeated hospital admissions.[3]

Last week, representatives of the College met with Blue Cross and Blue Shield Association representatives to urge their coverage of mammographic screening. We also plan to meet with the Health Insurance Association of America in the near future to discuss coverage of mammographic screening.

The College would also support Medicare's coverage of mammographic screening. According to the Health Care Financing Administration (HCFA) there are approximately 17.5 million women coverd by Medicare in the United States. If all the

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[1] American Cancer Society, "1984 Facts and Figures." New York: The American Cancer Society, 1983.

[2] John L. Young, Jr., Constance L. Percy, and Ardyce J. Asire (eds.), "Surveillance, Epidemiology, End Results: Incidence and Mortality Data, 1973-1977." U.S. Department of Health and Human Services, NIH Publication No. 81-2330, June 1981.

[3] K. tokita and K. Colburn, "Cost of Breast Cancer," unpublished study from Torrance Memorial Hospital Breast Examination Training Center in California.

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women covered under Medicare were to have a yearly mammographic screening, it is estimated that it would cost in the range of $879 million to $1.75 billion.

EXPERTISE

Radiologists are uniquely qualified to perform mammographic screening. They possess the expertise of imaging equipment, receptor systems, radiation physics, and dosimetry plus understanding of the anatomy of the breast. Mammographic screening should be performed under the supervision of a radiologist with demonstrated experience and competence in mammography. Expertise is needed in the actual imaging and interpreting the images.

Radiologists completing their training in the past 10 years received formal training in mammography. Continuing education classes, like those offered by the College provide training in new modalities and changing technologies. Radiologists not originally trained in these modalities or technologies are brought up to speed very rapidly and thoroughly upon completion of these classes.

SUMMARY

Mammography has made a highly significant contribution in the detection of breast cancer in women. A mammogram performed under the supervision of an experienced radiologist coupled with a clinical examination has literally made the difference between life and death in thousands of women.

The existing controversy with mammographic screening concerns its use with younger women. The guidelines issued by the College and other professional medical organizations recommend a yearly mammographic screening for women over 50. As the majority of Medicare participants are 65 or over, there should be little question as to the medical need or effectiveness for mammographic screening for these women.

One of the challenges that remain is to make mammography available to as many women as possible. One of the ways radiologists are doing this is to seek support within communities. The American Cancer Society has proven to be a valuable partner with community screening projects. It is vital to maintain the cooperation of College members in the public-spirited screening projects of the American Cancer Society. To provide the benefits of screening to all, regardless of income, is in the highest tradition of medicine and radiology.

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GUIDELINES FOR MAMMOGRAPHY

The American College of Radiology (ACR) Committee on Mammography under the Commission on Diagnostic Radiology, has prepared a current version of the guidelines for mammography originally published in the ACR Bulletin, Vol. 32, No. 8, August 1976. At the outset, it should be emphasized that this does not materially depart from the original statement.

Mammography has made highly significant contributions in the detection of breast cancer in symptomatic women at any age and in the screening of asymptomatic women fifty years of age or older. However, screening mammography in women under age 50 is less clearly established because of the lack of supporting data from controlled randomized studies and hypothetical projections of radiation risk.

THE BASIS FOR THESE CONCERNS ABOUT SCREENING MAMMOGRAPHY IN WOMEN UNDER AGE 50 ARE:

1. The data from the breast screening (physical examination and mammography) project of the Health Insurance Plan of Greater New York in the early 1960's revealed identical mortality for the study group (those screened with physical examination and mammography) and the control group (no screening) for women under 50 years of age. There was no separate assessment of physical examination versus mammography. However, very few cancers were found by mammography in this age group.

2. The reported increased incidence of breast cancer in: a) women exposed to the atomic bombs in Japan at the end of World War II; b) women exposed to varying amounts of flouroscopy during the management of tuberculosis; c) women with post-partum mastitis treated with radiation therapy; and d) a series of Swedish women who received high dose x-ray therapy for benign disease.

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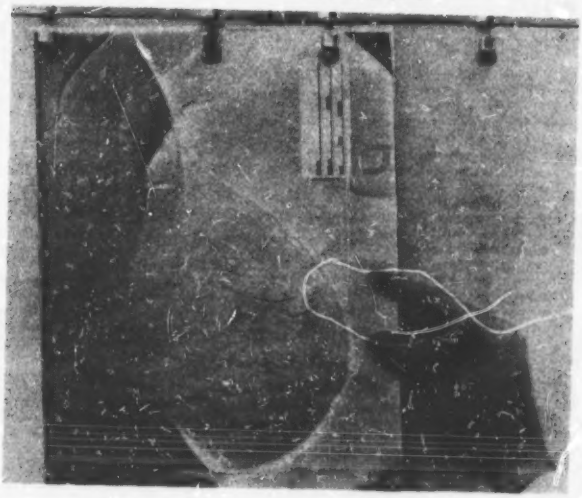
3. The Committee on Biological Effects of Ionizing Radiation (BEIR) of the National Academy of Sciences has indicated that the risk of low doses of radiation causing breast cancer is small but they have speculated that it may never be zero (the possibility of zero is not excluded by the data). This is based upon extrapolation from high radiation dose data (low dose data are lacking). Considerable disagreement exists concerning these conclusions.

HOWEVER, IN RESPONSE TO THESE CONCERNS:

1. Results from screening at the 29 ACS-NCI Breast Cancer Detection Demonstration Project (BCDDP) centers in the late 1970's indicate that approximately one-third of the breast cancers occurred between the ages of 35 and 50 and that most of these lesions were either in situ or did not involve the regional lymph nodes. Most of these cancers were detected by mammography and a much higher percentage were detected by mammography alone than by physical examination alone.
2. There has been progressive and significant improvement in the quality and diagnostic accuracy of optimum mammography and there has been marked reduction in radiation dose (this should not exceed one rad at the mid-breast with a two view examination).
3. While the risk of irradiation from optimum mammography is immeasurably small at all ages, the linear, no threshold response model seems to be a conservative method for estimating population risk for women under the age of 40. However, the available data strongly suggest that the risk for breast cancer induction by radiation is much smaller, if it exists at all, for women over age 40 at the time of initial exposure.

This improved mammographic ability to detect many small breast cancers, particularly in women aged 40-50, strongly suggests that substantially favorable benefit/risk ratios will apply to all women over forty years of age, so long as optimum mammographic technique and carefully monitored equipment are used. These guidelines are proposed as a summary of current informed opinion.



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I. Introduction

1) Mammography and physical examination are clearly complementary procedures and the end results are materially improved when the two diagnostic procedures are optimally combined. However, it is a basic tenet of cancer diagnosis and treatment to detect the primary tumor when it is small or non-palpable and mammography, appropriately performed, is the most effective non-invasive diagnostic tool for those purposes.

2) Although the presumed risks of radiation at current optimum levels of exposure (less than one rad to the mid-breast for a two view examination) are immeasurably small, continued efforts to reduce exposure should be made. However, this should not be at the expense of image quality which must be preserved to insure the best benefit-risk ratio.

3) Optimum and reproducible image quality are essential for accurate mammography interpretation. If xeromammography is the method of choice, it should be performed with a tungsten target tube and breast compressions during the x-ray exposure. If film-screen mammography is the method of choice, it should be performed only with an x-ray unit specialized for mammography. Each radiologist should have periodic monitoring of his equipment and procedures to assure that the patient's radiation exposure is being maintained at the lowest feasible level (less than 1 rad at the mid-breast for a two view examination) consistent with this optimum image quality.

4) At present, other imaging modalities such as thermography and ultrasound have not demonstrated the requisite sensitivity to substitute for mammography in screening or diagnosis. The presumed risks of radiation with mammography are not a justification for their use. Computerized tomography has had limited application, requires greater radiation exposure, and has some risk of adverse reaction to the intravenous injection of contrast. There is active research going on with these and a number of other imaging modalities.

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II. Care of Women with Symptoms

Mammography is an essential part of the evaluation of the patient and when optimally combined with physical examination, offers a high degree of accuracy.

Since the incidence of naturally occuring breast cancer is considerably higher in symptomatic women, the higher yield of non-palpable cancers results in even greater benefit-risk ratios than in asymptomatic women.

III. Screening of Asymptomatic Women

1) These recommendations for periodic screening mammography of women under age 50 are made because of accumulating data on benefits and the lead time gained by earlier detection. The American College of Radiology believes that these recommendations represent the most prudent advice based upon the best currently available evidence.

2) All women should be taught proper breast self- examination by age 20 and should have an annual physical examination of the breasts after age 35.

3) The first, or baseline, mammograms should be obtained by age 40. An earlier age is preferable when there is a personal history of breast cancer or a history of pre-menopausal breast cancer in the patient's mother and/or sisters.

4) Subsequent mammographic examinations should be performed at one to two year intervals determined by the combined analysis of physical and mammographic findings and other risk factors, unless medically indicated sooner.

5) Annual mammography and physical examination are recommended for all women over age 50.

IV. Research Programs

Screening mammography of asymptomatic women 40-50 years of age can detect significant numbers of non-palpable or minimal breast cancers and this indicates that a favorable benefit-risk assessment will be obtained. Nevertheless, research must be continued and encouraged to:

1) Obtain more data from controlled studies.

2) Improve methods for measurements of low level radiation.

3.) Further reduce radiation dose in mammography consistent with good image quality.

4) Determine the most appropriate age at which to begin screening for different risk groups.

5) Define women at high risk.

6) Establish the appropriate intervals for re-examination.

7) Define those mammographic findings that dictate the examination at a shorter interval.

8) Collect additional evidence on the benefits and risks of mammography.

9) Provide continuing education and training for radiologists and technologists, and current information for other physicians and patients regarding the role of mammography and other breast imaging procedures.

V. Future Statements

These guidelines are based on current available information. They will be revised when further information dictates and/or when more is learned about the control of breast cancer.

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BREAST CANCER SCREENING CENTERS

INTRODUCTION

Mammography is proven to be an effective procedure in identifying early malignant diseases of the breasts. Early detection of occult disease, before the development of clinical signs or symptoms, allows for wider options in treatment management. Early detection may substantially increase survival rates. Guidelines for the use of mammography have been issued by the American College of Radiology, the American Cancer Society, the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians.

SCREENING

Screening is the attempt to detect unsuspected disease in ostensibly healthy persons. Screening techniques should be sensitive, reasonably specific, harmless and inexpensive. If screening is all of these, it should be widely available.

The purpose of breast screening is to improve survival of women by detecting breast cancer at an earlier stage even when it is non-palpable. The methods available are breast self-examination, clinical examination and mammography. At this time, these are complementary procedures and the end results are improved when they are combined optimally. Competence is a major factor in the effectiveness of this combination, including the technical and interpretive expertise required for acceptable mammography. The value of periodic screening mammography in certain age groups of women, and in certain high risk segments of the population, has been well established. The demand for readily available, cost-effective facilities to perform screening mammography has grown rapidly over the past few years. To meet these needs, radiologists are urged to re-evaluate their equipment and technology for safety, accuracy and effectiveness; and to review their own credentials for mammography.

FACILITY STANDARDS

The radiologist must assure optimum and reproducible image quality. Accepted methods are those featuring low dose technique, e.g., xeromammography and film/screen mammography. Each requires specialized mammographic equipment, vigorous breast compression, and regular monitoring to ensure that the radiation exposure is at the lowest feasible level (typically less than 1 rad at the mid-breast for a two view examination). There can be no compromise with these technical requirements.

Other imaging methods such as ultrasound, thermography and transillumination have not demonstrated the requisite sensitivity to substitute for mammography, particularly as a single screening procedure. Recent ACR policy statements on ultrasound and thermography expand on this. Nevertheless, appropriate research with these and other imaging methods is encouraged.

PROFESSIONAL QUALIFICATIONS

Radiologists developed mammography. They possess the requisite expertise related to imaging equipment, receptor systems, radiation physics, and dosimetry plus understanding of the anatomy of the breast and as a result are uniquely qualified to perform mammographic screening. It is, therefore, recommended that mammographic screening be performed under the supervision of a radiologist with demonstrated experience and competence in mammography.

If physical examination is part of the screening process at a mammographic facility, physicians and allied health personnel involved should possess the requisite training and experience in the clinical evaluation of the patient. Every effort should be made to ensure that the clinical examination is of a quality sufficient to match existing community standards.

Ongoing programs to evaluate competence should be part of the screening facility policy. Correlation with tumor registries as a follow-up mechanism will be of assistance in determining false negative rates. False positive rates can be determined by comparison with pathology findings for those patients recommended for biopsy.

Under optimum screening conditions, the false negative rate should be very low. Higher false positive rates can be acceptable especially if a high percentage of the detected cancers are minimal. One should also consider the consequences of screening mammography:

True positive:	earlier detection and treatment and better prognosis
True negative:	reassurance of no cancer
False positive:	anxiety and time, cost and risks of more tests
False negative:	delay in diagnosis and treatment and worse prognosis

Radiologic technology personnel should meet voluntary certification and state licensure requirements, should have special training and sufficient experience to insure continuing competence. They should be particularly aware of

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pitfalls in radiographic positioning and technique. They should be familiar with acceptable radiation levels and with radiographic appearance of cancers.

COSTS

Historically, cost has been a significant deterrent to greater utilization of mammography as a screening examination. If screening is to benefit the population in general, radiologists should attempt to provide mammography at the lowest possible cost. Charges for mammography should be realistic, reflecting true direct and indirect costs, and a reasonable return for professional interpretation. An expected increase in patient volume resulting from the acceptance and promotion of mammography, should be considered in apportioning costs and return per examination.

Charges should reflect the service provided. Some facilities may elect to provide a screening examination at a different rate than that charged the referred symptomatic patient. Others may include physical examination as part of the overall service. Where level of service is a factor in setting charges, it is recommended that the service be itemized. Where a lower fee is established, it should be done with clear recognition that a lower standard of quality for the screening examination is unacceptable in terms of professional liability. Referring physicians could be induced to lower the cost for their patients by specifying the desired examination in those settings where a two-tier structure exists.

To minimize costs, routine inclusion of other modalities (e.g. ultrasound, diaphanography, thermography) in screening women for breast cancer is not cost-effective and should not be included in the basic screening service.

Despite best efforts, breast screening will likely remain priced above the means of many women. To make low-dose mammography available to those women, radiologists are encouraged to seek funding, support and volunteer participation from the community. To provide the benefits of screening to all, regardless of income, is in the highest traditions of medicine and radiology.

ACCESS AND REFERRAL PATTERNS

Historically, the practice of radiology has been based upon patient referrals from primary care physicians. In keeping with present policies and practices, it is clearly in the patient's best interest that a primary care physician be responsible for the overall care of the patient.

Screening mammography should be only part of the diagnosis and treatment of the patient. Medical history and physical examination are vital parts of a patient's care and management. The ACR recommends that, optimally, a patient should be referred for either screening or diagnostic mammography by another physician. The radiologist should be only one part of the medical team caring for the patient.

However, true screening relies upon direct access *by individuals without requiring* physician referral. Screening facilities which elect to accept walk-in patients must have well-developed procedures for notification to and follow-up to a qualified physician.

Patients should be asked for a name of a referring physician when registered at the screening facility. If they are able to provide a name, it is useful when possible, to establish communications with the physician before the procedure is performed. If the physician does not sanction the examination or the patient does not provide a name, it may be feasible for the radiologist to have an established pool of physicians who, on a rotating basis, would be willing to take such patients. The radiologist must be certain that the result of a positive mammogram is acknowledged by a primary care physician.

MEDICAL LEGAL ISSUES

The severe consequence of failure to obtain an early diagnosis of breast cancer, and the decision of women to obtain mammography on their own initiative, has changed significantly the historical reliance on the referral practice of radiology. When radiologists accept patients for screening procedures without physician referral, the radiologist becomes responsible, both ethically and legally, for assuring that another physician, and in most cases, the patient, has been told the results of the procedure, and where necessary, that recommendations have been made for follow-up.

A positive finding should be reported promptly *in writing* to a physician who will see the patient and assure that appropriate follow-up procedures are instituted. In all cases, appropriate acknowledgement of the notification should be sought. A copy of each positive report should be retained for five years or longer, as required by state law.

COMMUNITY RELATIONS

The American Cancer Society has proved to be a valuable partner in promulgation of the concept of screening mammography. Its Breast Cancer Detection Demonstration Projects furnished scientific validation of the value of screening mammography and this has been accepted, in a large part, by the medical community. It is vital to maintain this cooperation by the continuing participation of College members in the public-spirited screening projects of the American Cancer Society. This might be best accomplished by establishing close liaison between the state chapters of the College and the chapters of the American Cancer Society.

SUMMARY

Mammography has been shown to be effective in the earlier detection of breast cancer when optimally done and accurately interpreted. Challenges that remain are to obtain sufficient competent personnel and facilities to make this widely available at low cost. Under those circumstances, breast screening could save the lives of countless women.

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ON THERMOGRAPHY FOR THE DETECTION OF BREAST CANCER

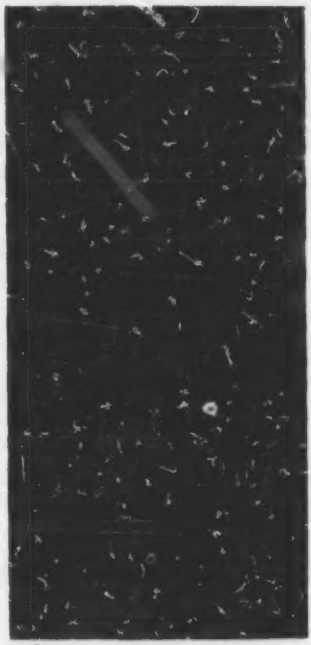
Thermography is a direct method of measuring temperature, either as discrete values or in the form of a visual image. Investigation of thermography has been encouraged because it is noninvasive and does not use ionizing radiation. Many variations of thermographic technique have been developed to evaluate the breast. At present, thermography of the breast is still an experimental procedure with no established clinical indications.

THERMOGRAPHY TECHNIQUES

Telethermography utilizes a photovoltaic detector to measure infrared rays emitted from the skin and converts this thermal signal into a skin temperature map, which is displayed on a television monitor in either black-and-white or color.

Liquid crystal thermography utilizes esters of cholesterol that change color in response to temperature changes. These "liquid crystals", encapsulated in mylar sheaths, are placed directly in contact with the skin to produce thermographic images. This technique is somewhat less sensitive in measuring temperature differences than telethermography but is considerably less expensive.

Computer-assisted thermography of the breast uses discrete temperature measurements taken at standardized locations on each breast; these thermal measurements then are entered into a computer programmed with one or several diagnostic pattern-recognition algorithms designed to calculate a "likelihood of malignancy" index. This approach is even less sensitive to temperature differences and is further subject to lack of reproducibility because it involves only a small number of (operator-selected) measurements. It does, however, produce objective results that are independent of observer.



ACR COUNCIL IN SESSION

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Graphic stress telethermometry utilizes computer-assisted diagnostic interpretation of two sets of temperature readings taken before and immediately after the patient's hands are immersed in ice water for 15 seconds. The rationale behind this technique is based on the theory that breast cancer detection by thermography is facilitated following cold stress, presumably since local thermography mechanisms (e.g. vasoconstriction) do not operate normally in areas of malignancy.

Microwave thermography measures microwave radiation naturally emitted from the breasts. Since microwaves have longer wavelengths than infrared emissions, they penetrate body tissues to a greater extent and therefore provide thermal information from subcutaneous and parenchymal tissues as well as from the skin surface albeit with considerably less spatial resolution.

PROPOSED CLINICAL INDICATIONS FOR THERMOGRAPHY

Thermography in its various forms has been under investigation for three decades. The thermal characteristics of breast disease have been described at length, but none of several existing sets of diagnostic criteria have received general acceptance. The bulk of thermographic experience has been with telethermography. Results using the other techniques are similar. Thermography has been proposed to serve several roles in the evaluation of breast disease. These are discussed below.

Evaluation of signs and symptoms that suggest the possibility of breast cancer. Studies of such "symptomatic" patients indicate that thermography operates at a high level of predictability only for advanced cancers (clinical Stage III, representing tumors 5cm or larger in maximum diameter). Almost all of these cancers are discovered by physical examination, and thermography does not play a meaningful role in their detection. For smaller, potentially more curable lesions, the frequency of thermographic identification is considerably lower, too low to be useful clinically and substantially less than that of mammography. Furthermore, even if positive, thermography does not localize a suspicious lesion because the site of thermal abnormality often does not correspond to the location of the underlying cancer. In summary, thermography should not be used to determine whether or not palpable breast masses should be biopsied.

Breast Cancer Screening. Most published reports that concern the ability of thermography to screen asymptomatic women for breast cancer are flawed by the absence of appropriate experimental controls; specifically lacking is the use of mammography among all patients studied. The most pertinent experience in the U.S.A. that evaluates the efficacy of thermographic screening is that of the Breast Cancer Detection Demonstration Projects (BCDDP). In this study of 280,000 patients, examined between 1973 and 1981, the cancer detection rate for thermography was 37 per cent in the first screening and 44 per cent in the second screening. These levels were clinically unacceptable when compared with the overall rate of 57 per cent for physical examination and 91 per cent for mammography. The BCDDP data also indicated that thermography is inadequate as a prescreening procedure (to indicate which patients should be studied by mammography), for had mammography been reserved only for those women with positive thermograms, 63 per cent of the nonpalpable cancers would have been missed. Thermography was discontinued as a routine procedure in 1977 on the recommendation of a special working group that was asked to review the BCDDP. In summary, thermography is ineffective as a means to detect clinically occult cancer, either as a stand-alone examination or as a "prescreener" to determine which patients need further study by mammography.

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Determination of breast cancer prognosis. Several studies have indicated a possible prognostic role of thermography, because breast cancers that produce grossly abnormal thermograms appear to be associated with substantially lower than average probability of survival. However, these studies are poorly documented, and their data have not been corrected for known prognostic indicators such as tumor size and histologic grade. As a result, the use of thermography for purposes of determining prognosis for a known or suspected breast cancer must be considered unproved and, therefore, experimental.

Prediction of breast cancer risk. Several reports have suggested that the abnormal breast thermogram may be useful as a predictor of breast cancer risk even though it appears to be of little clinical value as an immediate indicator of the presence or absence of cancer. Although these (retrospective) studies involve large numbers of patients, they appear to be poorly controlled and are based on data that have not been corrected for known risk factors. Other studies, smaller in scope but prospective in nature and better controlled, indicate that thermography has little if any ability to detect premalignant breast lesions. Currently there is insufficient evidence to support the use of thermography for cancer risk.

Relative Clinical Efficacy of Thermography

Because thermography does not employ ionizing radiation, some of its proponents consider the examination to be totally safe. However, lack of radiation risk does not justify the use of thermography. Indeed, when compared to the hypothetical risk from current reduced-dose mammography, utilization of thermography as a stand-alone test is seen to involve a much more serious risk, the risk that the false sense of security imparted by a "normal" thermogram might preclude further study by mammography, the only procedure currently capable of detecting substantial numbers of preclinical breast cancers.

The use of thermography in addition to physical examination and mammography involves no such risk. However, the addition of thermography to these established diagnostic examinations provides little clinically meaningful information and substantially increases the cost of medical care.

Conclusions

At present, thermography of the breast is still an experimental procedure with no established clinical indications.

The abnormal thermographic signal contains complex physiologic data that currently is poorly understood. Further research should be encouraged to elucidate the nature of this information.

The clinical use of breast thermography should be restricted to properly controlled prospective studies designed to evaluate clinical efficacy. These studies must be conducted according to published guidelines.

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Ms. OAKAR. Thank you very much, Dr. Thomas.

I am going to ask a few questions and then excuse the panel. I will probably ask more in writing for our record, only because we have another vote. As usual, things don't work out the way you want them to.

Dr. Lerner, let me ask you two questions. You did the study with Dr. Fisher, I believe, among others. That was really an important study. What you demonstrated in the study—correct me if I am wrong—which goes back to Senator Pepper's question about what is a woman to do, should a woman know what she should do, and so on. It's my belief that a lot of women have had unnecessary surgery possibly because they really were told by not all physicians but some that they needed a radical kind of approach. You gave the history of surgery, and so on. But in your findings, just to clarify this and to make sure that I understand. What you were able to demonstrate on your research into cases was that there was not an appreciable difference between women who had a simple lumpectomy compared to women who had more radical surgery. Am I pretty much summarizing it accurately?

Dr. LERNER. Correct. But let me go into it in a little bit more detail. One, I am not sure it is fair to say that women had unnecessary surgery. Given an option today, many women may still elect to have a mastectomy.

Two, the trial limited the size of the tumor. So, even today not necessarily all women can have less than a mastectomy. If the tumor occupies most of the volume of the breast, there is no way you could salvage a breast.

In that trial survival for less than a mastectomy—and the trial limited tumor size to 4 centimeters—was equal to having a mastectomy. So, the reward for finding a small cancer is, you have many more treatment options, and you have the ability to select a treatment of less than a mastectomy.

Ms. OAKAR. I don't want to put you on the spot, but one of the reasons I introduced legislation that would provide that a physician have to give a written statement—I think the cancer institute puts one out that would be fine—is that a lot of women really have a great fear. A lot of women don't really know what questions to ask. For example, a question might be: Could I have a lumpectomy, do you think? There are still surgeons—and I know you're not in a position to say this, but maybe you would like to comment, but I will say it. We had testimony from people who indicated that they had a lot of surgery and that now they are told they shouldn't have had all that surgery. All I am saying is that people ought to be informed, and your study provides a vehicle for information, it seems to me.

I would like to ask you what you mean by randomized prospective clinical trial, which the average lay person does not understand.

Dr. LERNER. I would be happy to answer that by going back to your statement. One, I was trained as a very radical surgeon. I was a cancer fellow, and so on. I was trained in Halsted-type surgery. I began to participate in clinical trials. There has never been a trial of any kind in surgery up until the modern era, when the National Surgical Adjuvant Breast Project became involved. When it came

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time for this trial, B06, less than a mastectomy, the standard was, and probably still is, a mastectomy. If I knew that they were equal, then I couldn't participate in the trial. If I knew one operation was better than another, I could not participate in the trial. It was the fact that I did not know that allowed me to participate in the trial. And women have to have informed consent.

Ms. OAKAR. And you need women, in other words, you need patients to be willing to participate in these trials. Otherwise, you don't really have the background.

Dr. LERNER. The real heroes are the women who participated, not us who performed the trial, because we didn't know the answer. They allowed the answer to come out. Their mother did not have the opportunity to participate in clinical trials. And these women are going to establish what will be best for their daughters.

Ms. OAKAR. Let me ask two other really quick questions, because I have less than 10 minutes to get down to the vote.

Dr. Powers, maybe I will ask you, or whoever wants to answer this. What can we do to make it relatively inexpensive for prevention? I mean, we are hearing that Pap tests now are much less expensive because more are done, and all that. What can we do to make it less expensive, so that we do the screening and, as you said, Dr. Strax, the examination is important as well. We don't want to mislead anybody here. Doctor?

Dr. POWERS. I would like to share the answer with Dr. Strax. I believe the first thing is to get the awareness that there is a possibility to do better than we have done in the past. And I think that that is what a number of my colleagues have done.

I think the second is to have a reimbursement that reimburses women for this procedure, or reimburses for that procedure. Now, that has to be done in a method that is going to be prudent in radiation and in money costs. I believe with Dr. Strax that it requires the physical examination as well as the x-ray examination. But the fact is that in a screening procedure it is presumably possible—is that correct, Phil—to do it for a lesser dollar.

Ms. OAKAR. And you demonstrated that, Dr. Strax, I believe.

Dr. STRAX. I think that the only way we are ever going to be successful in a practical way to do what you have in mind, which is to get the women of this country to have their breasts checked for early breast cancer, is to make it a communitywide affair. It has to be something set up in a community preferably by a group of interested women, lay women, women who have a need for this kind of study, for example, the United Order True Sisters. Let them get together and say, we've got to have a screening center in this community. Let them go out and raise the funds if necessary to set it up, get the dedicated physicians, act as volunteers so that the cost of operation becomes very low. They will stimulate the women to come. They will motivate the women and make them aware of the need.

I think, if we are going to rely on the medical profession to set up screening centers at the kind of costs that are charged, that a physician has to charge for his general medical upkeep, I think that we are going to have difficulty. It has to be something that comes from the bottom, and it should come from the women themselves.

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Ms. OAKAR. Let me ask Rose this, because your last line had to do with politicians. What do you think politicians should be doing, people like myself and the President and State senators?

Mrs. KUSHNER. Support the bills that have been introduced and enforce the laws that have already been enacted—like the Privacy Act. It is ridiculous that that this law is violated every day of the week, and nobody does anything about it. People are discriminated against for jobs, for credit, and for insurance.

Ms. OAKAR. That is really so ignorant, because people who have had cancer are living proof, like yourself, that you can be productive and probably even do a better job than someone——

Mrs. KUSHNER. But I can't get life insurance, and I could not get credit if my husband didn't endorse it. I am at high risk. I am at high risk of leaving a store with an unpaid debt. I could not get insurance. I have not been able to get a charge account in my own name.

Ms. OAKAR [continuing]. That is wrong. That's a civil rights issue——

Mrs. KUSHNER. The other thing I want to do, I have been trying to start a national breast cancer information organization around the country. Breast cancer is the only major disease that does not have a national organization. We do not have a Jerry Lewis. We do not have a Marlo Thomas. We do not have an Elizabeth Taylor. We must all get together and get some political clout and make all of you people——

Ms. OAKAR [continuing]. You just have Mary Rose Oakar, what are you going to do, right?

Mrs. KUSHNER. Yes, and that's fine. But you don't have the money.

Ms. OAKAR. That's for sure.

On that note, let me thank all of the witnesses. Good luck to you as well, Ms. Blum. We will conclude as soon as I run down to vote, with Alan Rabson, Director of the Division of Cancer Biology, and Dr. Greenwald. They are two really outstanding witnesses.

[Recess.]

Ms. OAKAR. We are going to resume the hearing. You will be happy to know we just supported the Health Research Bill. If I didn't vote on that, I knew you would never forgive me. It passed overwhelmingly.

We are happy to have with us Dr. Alan Rabson, who is the Director of the Division of Cancer Biology and Diagnosis, accompanied by Dr. Peter Greenwald, Director of the Division of Cancer Prevention and Control for the National Cancer Institute, National Institutes of Health in Bethesda. We are proud to have you here. Thank you, Doctor, for coming.

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PANEL FOUR—THE FEDERAL RESPONSE; CONSISTING OF ALAN S. RABSON, M.D., DIRECTOR, DIVISION OF CANCER BIOLOGY AND DIAGNOSIS, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH; ACCOMPANIED BY PETER GREENWALD, M.D., DIRECTOR, DIVISION OF CANCER PREVENTION AND CONTROL

STATEMENT OF ALAN S. RABSON, M.D.

Dr. RABSON. Thank you. We finally have come to the Federal response. I would like to explain that I am a pathologist and a virologist. I came to the National Cancer Institute in 1955, 30 years ago, and I have spent all of my time since then fighting what Senator Pepper referred to as the monster, cancer.

It really is a pleasure to be here to present an overview of breast cancer from the perspective of the NCI. I have a written statement which addresses the following areas, not just detection, but basic research, cause and prevention, screening, detection, diagnosis, and treatment. Because of the time constraints, I would like to submit the whole statement for the record and briefly discuss some of the highlights with you.

You heard over and over again that breast cancer is a major killer of American women. And you have heard again and again that 1 in 11 women will have breast cancer in their lifetime. I want you to understand that all of us at the Cancer Institute, the scientists, the physicians, every one of us, will be touched by this disease or has already been touched by it. It will strike our mothers, our wives, our other loved ones and our friends. We desperately want to learn how to prevent this disease and how to treat it effectively if it strikes.

We have learned much already, and there's a lot we can do, but there is still so much more to learn and so much more to do. People often ask why we can't deal with cancer the way we have done with infectious diseases such as poliomyelitis and smallpox. Our greatest successes in medicine have indeed been with infectious diseases. There the enemy is a foreigner, a microorganism that enters the body from without. We can develop public health measures to keep the organism out. We can develop vaccines to stop it from growing if it does enter. And we can develop antimicrobial drugs that will kill it once it starts to grow.

In human cancer, however, with few exceptions the enemy arises from within. Cancer appears to be a disease of cell regulation. Normal cells have their growth and their ability to move around within the body under rigid control. In cancer these controls are somehow lost. The cells escape from normal regulation. Our task and the thing that has concerned us through these years is to try to understand how normal cells are regulated, what goes wrong in cancer, and then to either prevent it or to fix it.

Since cancer does seem to be a disease of abnormal cell regulation, I strongly believe that what we learn about any cancer cell will help us to understand and control breast cancer cells. And what we learn about breast cancer cells will surely help us to understand the problems of colon cancer, lung cancers, prostate cancer, and other cancers.

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Let me give you a few examples of how we are approaching problems in cancer research and the progress we are making. One of the most exciting areas which you discussed last year in your hearings is the application of monoclonal antibodies to cancer. People don't often think about it, but where did monoclonal antibodies come from? In 1952, 3 years before I came to the National Cancer Institute, Dr. Michael Potter, a young physician from Charlottesville, came to the National Cancer Institute in Bethesda to learn to do cancer research. Rather than attack the problem of human cancer directly, he chose to work with the laboratory mouse because years of research had developed a powerful understanding of the genetics of the mouse. He chose to work with plasma cell tumors, the equivalent of human multiple myeloma, and these are the cells that produce antibodies.

He developed the cell lines and the understanding of immunogenetics that were subsequently to be essential for producing monoclonal antibodies. Some time later, researchers in Japan and England developed methods for taking two mammalian cells and fusing them together into one. That was also to be essential.

Ms. OAKAR. Doctor, could you define monoclonal antibodies for me?

Dr. RABSON. An antibody is a molecule that attacks a foreign substance in the body. And monoclonal antibodies are antibodies that are pure and attack only one substance. The big thing about them is that it is possible to make large amounts of the monoclonal antibodies. Our goal is to take a tumor cell, find something different about it, something that the antibody system can recognize, and then we can produce with this monoclonal antibody technique unlimited amounts of a highly specific purified antibody. Kohler and Milstein, who won the Nobel Prize a few years ago and shared the Lasker Award last year with Michael Potter, developed the technology for producing these very specific antibodies in unlimited amounts.

Dr. Jeffrey Schlom, who has accompanied me, was one of the first people to make monoclonal antibodies to breast cancer cells.

Ms. OAKAR. Is the doctor here?

Dr. RABSON. Yes, that is Dr. Schlom.

Dr. Schlom's antibodies are now used in a number of centers. We are working at trying to develop applications for them. We already know we can use them in some diagnostic situations. We can take aspiration biopsies of the breast, where it is very difficult for the pathologist or the cytologist to pick out single tumor cells in the midst of other cells. With Dr. Schlom's monoclonal antibodies, we can identify very specifically the malignant cells. He is also using it on pleural fluid aspirations and other things. We are busy trying to figure out how to use them now in imaging tumors to improve diagnosis. Hopefully, when we develop all of this specificity, we will put things on the antibodies, either drugs, toxins, or radioactive substances, which will go after the cancer cells and, hopefully, improve cancer treatment.

There is another example again that was mentioned last year that we are very excited about, the oncogenes. Much of what we have in oncogenes research we owe to the original support of the cancer virus program by the Congress in 1964. Out of this research

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came an understanding that at least in animals there were certain viruses that could transform a normal cell into malignancy. From that, we got to the point that we were able to determine that one or maybe two genes in the virus were able to carry out this malignant transformation. And those genes then were called oncogenes.

They are genes then that have the ability to enter a cell and to transform it to malignancy. We then found out that many of the oncogenes were actually normal genes that had been somehow perturbed or altered. One of the things we think may happen in many cases of cancer is that a normal gene is somehow altered and begins to function as an oncogene. One of the most widely studied oncogenes now is called RAS, R-A-S, because it was isolated first in a virus from a rat sarcoma, by people interested in animal tumors.

Subsequently, while work was going on on RAS, it was found in the cells of a human bladder cancer from a patient with an advanced bladder cancer. That RAS gene has been extensively studied in the laboratory. We are beginning to understand something about how it works and what it does. Dr. Schlom, again, has made highly purified monoclonal antibodies to the substance made by the gene. He has been able to use it to identify areas of early malignant transformation. We are also trying to use those antibodies in diagnosis.

A very exciting thing has happened recently in breast cancer. Dr. Mark Lipman, who is a brilliant scientist clinician at the Cancer Institute, who runs our intramural breast cancer program——

Ms. OAKAR. Are these Federal employees?

Dr. RABSON. Yes, these are Federal employees.

Ms. OAKAR. I don't mean to interrupt you, but I chair a committee relative to Federal employee benefits. The American people don't realize sometimes that when we are talking about Federal employees, we are talking about Government workers like our postmen, everyone from that person to an astronaut to someone doing cancer research. I just want to assure you that I am going to fight to save your pension rights and all those other things. You probably could make an awful lot more money in the private sector than you are making as Government workers. But look at these brilliant things that you are doing that will save so many people.

I just had to put on my other hat for 1 minute and say that.

Dr. RABSON. We appreciate your support.

What Dr. Lipman has just recently shown is, this oncogene that came from a human bladder cancer, or from a rat sarcoma, when put into breast cancer cells that are hormone responsive, ones that respond to estrogen deprivation, that putting the RAS oncogene into those cells makes the hormone responsiveness go away. We have known for years that women who have estrogen sensitive tumors sometimes have their tumor change to a nonsensitive tumor. And this is the first insight we have had into how this change can take place.

Armed with this now, you can be sure that our next goals will be to try to figure out how it does this and how we can prevent it, if it is——

Ms. OAKAR. So, you are inching your way toward trying to find some kind of a cure.

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Dr. RABSON [continuing]. This is it.

Ms. OAKAR. That is great. I think the American people would rather have you do that than have their money wasted on a lot of other things, let me tell you. I think this is terrific.

I didn't mean to interrupt you, go ahead.

Dr. RABSON. I don't want to keep you too long, but in the written statement I have discussed other examples of the progress we are making. There is no question that early detection can make a difference both in survival and in the options for less disfiguring treatment. You have heard a lot about that.

Last month in Bethesda we had a consensus conference on chemotherapy. We did an analysis of the clinical trials worldwide. It showed conclusively that the use of anticancer drugs and antiestrogen therapy have increased survival in certain breast cancer patients. We know this is a promising area. We are trying to develop even better new methods for treatment.

I would like to end, before questions, with this last statement. I know that all of you and the American people are impatient with us because you feel we are moving too slowly. I want you to know that we are impatient with ourselves. But we are trying our very best to tackle this problem.

A number of years ago, Arthur Kornberg, who is a Nobel laureate and a professor of biochemistry at Stanford told this story at a meeting. A professor of surgery was jogging by a lake one day. He saw a man drowning. He tore off his sweatsuit, swam over. After a struggle, he dragged the victim ashore and revived him. He went back to jogging but soon he saw another man drowning, and he went through the same maneuvers. By this time he was exhausted. But then he saw two more men in the lake drowning. Ready to jump in again, he noticed the professor of biochemistry walking along by the side of the lake, lost in thought, and apparently indifferent to the drowning men. The surgeon called to him to rescue one man while he went after the other. When the biochemist failed to respond immediately, the exasperated surgeon pleaded with him to do something. The biochemist answered: I am doing something. I'm trying to figure out who keeps throwing all these people in the lake.

Now, in our programs at NCI we are supporting both the surgeons and the biochemists and all the other members of the biomedical research team that I am sure will ultimately triumph over breast cancer.

And I wrote this before you said the nice things. But I wrote: With your help and support, I am sure that we will succeed.

[The prepared statement of Dr. Rabson follows:]

PREPARED STATEMENT OF ALAN S. RABSON, M.D., DIRECTOR, DIVISION OF CANCER BIOLOGY AND DIAGNOSIS, NATIONAL CANCER INSTITUTE, NIH

Mr. Chairman, members of the subcommittee: It is a pleasure for me to be here to present to you an overview of breast cancer from the perspective of the National Cancer Institute (NCI). My statement addresses the following areas: basic research, cause and prevention, screening, detection and diagnosis, and treatment.

Because of the time constraints, I will touch on important areas in my statement, and with your permission, I would like to submit a longer version for the record.

Breast cancer has long been a major killer of American women. In 1985, there will be 38,400 deaths from breast cancer and 119,000 new cases will be diagnosed.

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We have many reasons, which I will describe today, to be optimistic that mortality from this disease will be lowered in future years. In fact, we can rejoice at real progress against this devastating disease. The good news includes:

Early detection of breast cancer can make a difference both in survival and in options for less-disfiguring treatments. We urge women to do breast self-examination, to have medical checkups, including periodic mammography for women over 50, and to get prompt medical care. These steps improve their chances for cure.

Clinical studies have continued to support the trends away from the mutilating Halsted radical mastectomy and toward breast-saving surgical techniques. Today, many women with early-stage breast cancer do not have to face the loss of a breast. They have the option of lumpectomy followed by radiation therapy.

For women who do have a mastectomy, there is the option of breast reconstruction.

We have learned a great deal about the psychosocial as well as medical needs of breast cancer patients. With this understanding comes wiser support of the patient during treatment and more effective rehabilitation. Her return to a normal lifestyle can be made smoother.

An analysis of clinical trials worldwise carried out this September has shown that chemotherapy—the use of anticancer drugs—and anti-estrogen therapy have increased survival in certain broad groups of breast cancer patients. We know this is a promising area.

As researchers work to keep up the momentum of progress against breast cancer, let me briefly turn to some exciting areas of basic research:

BASIC RESEARCH

Researchers are unraveling the complex biology of breast cancer and important advances are being made—advances that may have major impact in the prevention, detection, diagnosis and treatment of this disease.

The most intense areas of investigation include:

1. The use of monoclonal antibodies to define and detect breast cancer markers on the cell surface. This could help with both detection and treatment.

2. The identification and characterization of oncogenes and other elements in the cell that may play a role in the cause of breast cancer.

3. The role that growth factors and tumor factors play in cancer cell growth.

4. The identification of the biochemical mechanisms that allow cancer cells to metastasize or spread, ultimately causing death. This information could be used to develop better strategies for diagnosis and treatment of breast and other cancers.

Monoclonal antibodies: The development of monoclonal antibodies designed to "home in" on specific cancer cells has led to the identification of new tumor markers associated with breast cancer, and to the generation of agents that may be useful in breast cancer treatment.

Perhaps the most immediate applications of monoclonal antibodies in the management of human breast cancer will be their use to detect hidden tumor cells and to characterize or fingerprint cancer cell populations. For example, a recent study has shown that a particular monoclonal antibody can help detect breast cancer cells in numbers far too small to be detected by any other method. This monoclonal antibody test is already being used in several institutions to complement standard procedures to diagnose hidden breast cancer.

A major concern in the evaluation of the primary breast cancer patient is the presence or absence of tumor in regional lymph nodes. At this time, the standard procedure is to remove the nodes at the time of lumpectomy or mastectomy, and then evaluate them for the presence of cancer cells. The absence of cancer cells in nodes is a favorable sign.

A monoclonal antibody, or a mixture of monoclonal antibodies, coupled with diagnostic isotopes or dyes could provide a less invasive and more sensitive method of detecting tumor cells in nodes, particularly in nodes which cannot be reached without extensive surgery. Monoclonal antibody tagged with radioactive labels would be administered and the patient monitored by a gamma camera to find lymph nodes with cancer cells. Extensive surgery would not be needed. Studies of these techniques are now being started in several institutions.

A major issue in the management of the breast cancer patient is detection of cancer that has spread. The appearance of metastasis in breast cancer patients has been known to occur 10 or more years after surgery. Survival curves of patients who have been effectively treated with adjuvant chemotherapy give us reason to believe that, for them, late metastasis may be much more rare. The administration at regu-

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lar intervals of monoclonal antibody coupled with isotopes may be able to detect cancer spread early. Studies ot this will start within the year.

Also, the same monoclonal antibody (coupled to different isotopes) may be used in both diagnosis and treatment. In fact, the diagnosis technique can serve as a prediction of the amount of treatment needed with monoclonal antibody coupled to killer isotopes.

Studies are under way to see how various monoclonal antibodies react selectively to cancer cells versus normal tissues. The results will be used in later treatment studies.

Oncogenes: The discovery of oncogenes—a group of genes that appear to be involved with cancer development—has led to a new understanding of cancer. Approximately 30 oncogenes have been identified from various cancers of animals and humans.

Recent studies have shown that the majority of human breast cancers contain elevated levels of a product of one of these oncogenes. Oncogene research may help determine the cause of breast cancer and how normal cells become cancer cells. Researchers are investigating the prospect of developing materials that could block the function of oncogenes or their products. This could prevent the change from normal to cancer.

Growth factors: Recently, epidermal growth factor and tumor growth factor have been isolated from both rodent and human breast tumors. We are studying the roles these substances may have in stimulating the growth of breast cancer cells.

Metastasis: Cancer researchers are striving to understand the fundamental mechanisms that control cancer cell invasion and metastasis. If metastasis could be blocked or prevented, most cancers would not be life-threatening. Much remains to be learned about how cancer cells spread and why they are able to evade the body's natural defense mechanisms; however, recent research has shed some light on these processes.

Noncancerous tumors always have basement membrane separating them from normal tissue. In contrast, cancerous tissue always has general changes in the organization, distribution and quantity of basement membrane. NCI scientists have found that the amount of basement membrane decreases significantly as cancer cells progress from a noninvasive to invasive state.

Cancer cells appear to have special binding factors on their surface that enable them to attach to basement membrane. Human breast cancer cells that metastasize at a very high rate have many binding factors on their surfaces. These factors seem to allow the cells to attach to a protein called laminin, which is found only in the basement membrane. By blocking these binding factors, scientists hope to inhibit or eliminate this avenue for metastasis formation.

Cancer cells break through the basement membrane by secreting special enzymes, or by causing normal cells in the area to secrete enzymes that cut holes in the basement membrane. Some of the cells in all human breast cancers contain these enzymes. The cells producing the enzymes probably are the ones that actively invade. Testing for and measuring the amount of enzymes present may be a way to predict the aggressiveness of human breast cancers.

In the final step, cancer cells move forward through the holes in the barrier and gain access to blood or lymph vessels. The cycle must be repeated for tumor cells to exit the blood or lymph vessels and begin growing into metastases.

CAUSE AND PREVENTION

Breast cancer has been the topic of a large number of epidemiologic investigations, which have identified a variety of risk factors. It is well established that age exerts major effects, with the risk increasing continually throughout a woman's life. The risk of breast cancer also gradually increases among migrant populations who move from low-rate countries, such as Japan, to high-rate countries, such as the U.S., suggesting the importance of environmental factors, notably those related to lifestyle practices such as diet.

Furthermore, a woman whose mother or sister has had breast cancer is at approximately twice the risk of those without such a family history. Risks may be even further elevated if more than one relative is affected, if the relative has had cancer in both breasts, or if the disease occurred at a young age.

Other personal factors associated with elevations in risk include a history of certain types of benign breast disease. We now have recent information regarding which types of benign disease are predictive of future cancer. A number of factors relating to menstrual and reproductive history also appear to influence risk, probably through hormonal mechanisms. Risk increases with early age of first menstru-

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ation, a late age at the birth of the first child, and menopause at an advanced age. Conversely, an early surgical menopause that involves removal of both ovaries has been associated with a reduced risk.

Finally, there is some evidence that obesity is related to high breast cancer rates. There has been much discussion about possible dietary influences. Continued research is needed on specific nutritional factors, nutrient interactions, and biologic mechanisms related to diet and cancer. General recommendations to keep trim and reduce dietary fat may have benefits for breast cancer as well as several other important diseases, and seem prudent while the research continues.

Several recent hypotheses have been raised regarding possible associations between breast cancer and alcohol, smoking, and caffeine, but a number of studies have failed to show this. The relationship of hormonal drugs, including oral contraceptives and menopausal hormone replacement therapy, has received particular attention. Overall, studies do not show an increased risk of breast cancer due to oral contraceptive use. However, some studies suggest a possible effect on certain subgroups of women. Those subgroups of highest concern include women who have used the pill at early ages, women who have used the pill or menopausal estrogens for extended periods of time, and users of hormones who are already at high disease risk by virtue of other factors, such as a family history of breast cancer.

The National Cancer Institute has an active progam of intramural research aimed at identifying factors that cause breast cancer. These factors include those mentioned above—the relationship to risk of hormones, smoking, alcohol, and caffeine—as well as anthropometric measures at various life stages. The populations being studied include participants in a nationwide screening program as well as members of several prepaid health plans.

The clarification of nutritional factors is of high priority. Previous difficulties in identifying specific nutritional factors have been thought to relate to the homogeneity of the diets of the populations studied. To examine affects of a more heterogeneous diet as well as to assess how risk is affected by changes in diet at various ages, a study of young Oriental-Americans has been initiated. This study is attempting to relate risk both to dietary interview data as well as to specific biochemical measures of various nutrients and internal hormones.

In defining mechanisms of carcinogenesis, the National Cancer Institute emphasizes the interdisciplinary approach, including the incorporation of biochemical probes to define more precisely causative events, including the interaction of nutritional, endocrine, and genetic determinants.

PREVENTION

Internationally, there is a direct correlation between per capita consumption of fat and breast cancer mortality. For example, a high-fat diet (about 40 percent of total calories) is common in the United States and rare in Japan and Italy, which exhibit a much lower incidence of breast cancer. Experiments on animals also indicate that dietary fat promotes tumor development in the breast.

NCI recently began two clinical trials, one to test the impact of a low fat diet in preventing breast cancer in women who are at high risk for the disease, and the other to test the impact of the same diet in preventing cancer recurrence in women with Stage II breast cancer. The first study is being started with approximately 12,000 women who are considered to be at high risk for developing breast cancer. The second study of a low-fat diet (15 percent of calories) in Stage II breast cancer will involve approximately 2,000 patients in a 5-year study. Full implementation of these studies will be determined after completion of a feasibility phase in mid-1986.

Chemoprevention is the introduction of selected micronutrients, such as vitamins in the diet, to try to prevent cancer. Laboratory and epidemiologic data indicate that various agents can halt or reverse cancer progression in animals and may reduce risks in humans.

Several compounds that have demonstrated the ability to inhibit breast cancer are being evaluated in animal systems. These include the synthetic retinoid 4-HPR, and the combined effect of 4-HPR and tamoxifen, a hormonal drug that functions as an anti-estrogen. Results of those preclinical studies in animals will serve as the basis for possible further evaluations in humans.

The success of tamoxifen in delaying recurrence and reducing mortality when it is used as an adjuvant treatment in breast cancer has stimulated interest in the possibility that tamoxifen might be useful for chemoprevention in women who are at high risk of breast cancer. For example, the drug may be able to prevent or delay the onset of breast tumors in the non-affected breast of women with previous breast cancer. Continuing research on the potential use of this agent for cancer prevention,

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together with further preclinical evaluation for potential adverse health effects, is needed.

SCREENING/DETECTION AND DIAGNOSIS

There is great potential to reduce breast cancer mortality with the systematic application of screening procedures. The size of the mortality reduction will depend on characteristics of the population, the screening procedures adopted, and the compliance with the screening regimen. Based on four studies with mammography and physical breast examination and one study with mammography only, screening women over age 50 with these procedures can reduce breast cancer mortality at least 30 percent. About 38,400 female deaths are anticipated from breast cancer in 1985. An effective screening program could reduce this number by 10,000 lives, and the number of lives saved would grow as the population ages. Based on the very consistent trends in breast cancer incidence and mortality, it is unlikely that many breast cancer deaths are now avoided through full use by American women of mammography and/or breast physical examination.

The landmark study of the effectiveness of breast cancer screening was done by the Health Insurance Plan (HIP) of New York. This study enrolled 60,000 women in a controlled clinical trial in a defined population and estimated a 32-percent reduction in breast cancer mortality after a 10-year followup. The other recent randomized controlled trial to investigate screening, using mammography only, showed strikingly similar results for 162,981 women enrolled in a study in Sweden. A mortality reduction of 31 percent was demonstrated based on 7-year followup.

Several other studies have been completed which, although not randomized trials of screening, support the potential of screening for mortality reductions. The Breast Cancer Detection and Demonstration Program (BCDDP) and two recent case-control studies showed results consistent with the positive findings from the HIP study.

The data on the current use of breast cancer screening technologies is limited and not necessarily reliable. Specifically in regard to mammography, a Gallup poll suggests that approximately 14 percent of women have had a mammogram in the past year, with 41 percent of women ever having had a mammogram. To get more information about screening practices, the NCI is planning a survey of cancer control knowledge, attitudes, and practices as a supplement to the 1987 Health Interview Survey to be carried out by the National Center for Health Statistics. The data from this survey will be available by late 1988.

The NCI has continued its support of studies and analyses in breast cancer screening. These include:

The Breast Screening Long-Term Follow-Up Study involves 64,185 of the more than 280,000 women who are enrolled in the BCDDP.

This study provides an excellent opportunity to determine estimates of risk and provides detailed information on the biology and natural history of breast disease for defined groups within a screened population. The study is in its fourth and fifth year of the 5-year followup. Overall, the followup has been very successful, with a 97.5 percent success rate.

A workshop will address important issues relevant to the breast cancer screening and follow-up data. Hypotheses also will be developed with respect to prevention intervention studies that could be done in the follow-up cohort or group.

Data from several cancer screening studies are being analyzed to gain a better understanding of the impact and consequences of such screening in various population settings. These data bases also provide the opportunity for the testing and development of new techniques for data analysis. Patterns of cause of death among breast cancer cases are being studied to distinguish between postponement of death and cure.

Serum and background information have been collected from over 11,000 women for evaluation of biological markers for breast cancer. Samples are available from 6,300 asymptomatic normal women and 3,000 women with benign breast disease, most with documented 2-year, disease-free followup, as well as from 1,500 breast cancer cases.

We also are supporting the feasibility of Magnetic Resonance Imaging for early detection of breast cancer.

TREATMENT

Over the last 20 years, progress in treating breast cancer has been substantial. In 1894, surgeon William Halsted devised the operation to remove the entire breast, lymph nodes under the arm, and chest muscles. This was based on the belief that cancer spreads directly into adjacent tissues. Then in the 1960's, Dr. Bernard

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Fisher pioneered studies revealing that cancer cells spread through the bloodstream, and identified the systemic nature of the disease. Since then, the trend has been away from the traditional Halsted radical toward less and less disfiguring surgeries.

In the early 1970's, the National Surgical Adjuvant Breast Project (NSABP), an NCI-funded consortium of more than 100 medical centers, undertook a major study of less extensive surgery for breast cancer. Under Dr. Fisher's direction, results of this study, involving 1700 patients, led to major revisions in surgical practice for breast cancer. At an NIH Consensus Development Conference in 1979, experts in breast cancer agreed that for women with localized disease, the Halsted radical mastectomy should be set aside in favor of a procedure that preserved the chest muscles. The conference also endorsed doing the biopsy separately from the definitive treatment, in a two-stage procedure.

Another 1979 NIH Consensus Development Conference confirmed the usefulness of a test for the presence of hormone receptors in breast cancer tissue. This important tool can help to identify breast cancer patients most likely to respond to hormonal treatment and provide important information to forecast the course of the disease.

Meantime, also during the 1970's, cooperative groups of researchers in this country and around the world began intense studies of the use of anti-cancer drugs following surgery, known as adjuvant chemotherapy, to treat breast cancer. Dr. Fisher's group began with a modest clinical study of one drug back in 1958. Now, thousands of women have been enrolled in studies of drugs and drug combinations. NCI has funded many large studies of chemotherapy for breast cancer including those of the National Cancer Institute of Milan, Italy. In July 1980, an NIH Consensus Development Conference affirmed the value of chemotherapy for premenopausal patients with evidence of cancer in the underarm lymph nodes.

Earlier this year, Dr. Fisher reported results of another major national study, indicating that breast-saving surgery—lumpectomy—followed by radiation as part of the primary treatment, is as effective as mastectomy for early-stage patients followed for 5 years. These patients will be followed longterm, to be sure, but all of this is part of some very good news for women—news of the live, intact, cancer patient.

In September 1985, mortality data of breast cancer patients in chemotherapy and hormonal treatment clinical trials worldwide were carefully analyzed by experts led by Richard Peto of Oxford, and new guidelines for treatment were drawn up at an NIH Consensus Development Conference on Adjuvant Chemotherapy for Breast Cancer.

The analysis of mortality data, for example, indicated that adjuvant treatment of breast cancer patients under age 50 with chemotherapy could avoid about 25 percent of early deaths; that is, deaths within the first 5 years related to the breast cancer in this group. The analysis also indicated that when women over 50 whose cancer cells were estrogen-receptor positive received tamoxifen as adjuvant therapy, about 20 percent of early deaths are avoided.

Considering this and other scientific data, the Consensus Development panel considering adjuvant chemotherapy for breast cancer concluded that:

"Adjuvant chemotherapy and hormonal therapy are effective treatments for breast cancer patients. While significant advances have been made in the past 5 years, optimal therapy has not been defined for any subset of patients. For this reason, all patients and their physicians are strongly encouraged to participate in controlled clinical trials.

"Outside the context of a clinical trial and based on the research data presented at the 1985 Consensus Development Conference, the following statements can be made:

For premenopausal women with positive lymph nodes, regardless of hormone receptor status, treatment with established combination chemotherapy should be used.

For premenopausal patients with negative nodes, adjuvant therapy is not generally recommended. For certain high-risk patients in this group, adjuvant chemotherapy should be considered.

For premenopausal women with positive nodes and positive hormone receptor levels, tamoxifen is recommended.

For premenopausal women with positive nodes and negative hormone receptor levels, chemotherapy may be considered but cannot be recommended as standard practice.

For premenopausal women with negative nodes, regardless of hormone receptor levels, there is no indication for routine adjuvant treatment. For certain high-risk patients in this group, adjuvant therapy may be considered."

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Researchers today are unraveling the complex biology of the disease itself in order to design the most effective breast cancer treatments. With constant refinements in treatment, the NCI is making information on the state-of-the-art rapidly available to physicians through a new computerized cancer treatment information database called PDQ. In providing information to the public and patients, the Cancer Information Service (CIS) offices throughout the country have responded to almost two million inquiries since 1976. In 1983 and 1984, 64,000 calls—about 10 percent of all calls in those years—were about breast cancer. Women who need to know more about breast cancer need only dial a toll-free number to get the latest information. That number, 1-800-4-CANCER, connects the woman to the CIS, sponsored and supported by the NCI.

Mr. Chairman, this concludes my statement. I would be glad to answer any questions you may have.

Ms. OAKAR. Thank you very much, Doctor.

You have made a lot of progress. I don't think a lot of times we realize the progress that has been made in research. And I can say this as a good Democrat, but when President Nixon called for a war on cancer and provided an escalation of funds, that was positive. But in the last 10 years, if my figures are correct, we have decreased the funding—now listen to this. People ought to be outraged at our priorities here. You can't say it, but I will. We have decreased money for the National Cancer Institute, that serves as an umbrella, I think, for so many of the good things that go on along with the grants that you administer and all that, we have decreased it 20 percent, or in real dollars, $130 million.

Now, everything is relative, but $130 million is about one-fiftieth the cost of a cost overrun for a helicopter project for the military. You know, it's just crazy, our priorities. I think the American people ought to say, if we can destroy the world then, my goodness, we can give a few more of our tax dollars to people like yourselves so that you can get the very best people and attract them and provide for the very best grants so that we can lick cancer.

I was in Japan last year. They have as one of their national goals to have a cure for cancer by 1990. This is absolutely one of their national goals. So, they are channeling all this money into research for cancer.

Now, if Japan can do that, then we ought not to be—you know, here's the President of the United States who has cancer. Millions of women and men in this country and world get cancer. And we have such a small item in our budget for the work that you do.

I know you can't be self-serving and say any of that, but I am sure you felt the burden of the cuts and the limitation on grants, which I think is one of the most terrible things David Stockman—what a terrible legacy to leave and put that limitation on grants for people to provide for the research that is necessary, and so on.

I just think, with the resources you have, I just think you are doing a great job. I really do. But we have to give you better resources. I hope the American people will be outraged at the cuts in research. We are going to see more cuts if we pass this insane notion called Gramm-Rudman. That would be the first target, research, medical research in our country.

Anyway, enough of my editorializing. I just think a lot of times the public, the American people don't know what the ramifications are of priorities around here. They ought to know, because we have responsibility.

Dr. Greenwald, we would like to hear from you as well.

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Dr. GREENWALD. I did not prepare a statement, but I would like to add a few things.

Ms. OAKAR. Sure.

Dr. GREENWALD. I would like to emphasize that there are some things that we can do today to reduce risks of cancer. A woman may lower her chances of getting breast cancer through dietary changes. The reason we know this is that the frequency of cancer varies widely from country to country, tremendous differences. When people move from one place to another, they take on the risk of the place to which they move. For example, breast cancer is rare in Japan, but when Japanese women move to Hawaii or California their risk of breast cancer goes up.

There are socioeconomic differences in cancer rates that may be related to diet.

Ms. OAKAR. What should we be eating or not eating?

Dr. GREENWALD. Eat a variety of foods that are low in fat. That's the main factor related to breast cancer, and keeping trim. If you do those two things, it probably lowers your chances of getting breast cancer. It doesn't guarantee prevention, but fewer women would get breast cancer.

Ms. OAKAR. Green leaf vegetables and all those kinds of things.

Dr. GREENWALD. Also, increasing the fiber-containing foods in your diet like fruits and vegetables, whole-grain cereals, and whole-grain bread products also reduces cancer risk, primarily cancer of the colon and cancer of the rectum. So, these are some things we can do today.

In regard to research, we have for the first time in history human cancer prevention trials in progress. You talked earlier about clinical treatment trials. Equally important are clinical trials in cancer prevention. One of these trials focuses on women who have a very high risk of breast cancer; these women are randomized into a diet very low in fat, about half of the calories from fat that the usual woman eats. The women are then followed to see if there is actually an impact in lowering the occurrence rate of breast cancer.

There is another trial that deals with prevention of reoccurrence in women with local breast cancer that has extended to local lymph nodes.

We have a number of studies in the lab that show that cancer inhibition is possible in laboratory animals. We are doing the bridging studies to human prevention research——

Ms. OAKAR. What does that mean, cancer inhibition?

Dr. GREENWALD [continuing]. Stopping cancer from developing in the first place. For example, it's possible to cause bladder cancer in a rat. If you put a tube into the stomach of the rat and squirt in a particular cancer-producing agent, 40 percent of the rats will develop bladder cancer. By then feeding a synthetic compound related to vitamin A you can lower that risk from 40 percent to 5 percent. You can reduce the risk of mammory tumors in rats from 100 percent down close to 20 percent by feeding cancer inhibitors.

We think that there is enough laboratory evidence and human studies—the type of research called epidemiology—that we have started about 26 human cancer prevention trials. In these trials people are administered pills and compared with a placebo that

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looks the same and tastes the same to see if we can actually lower the cancer rates. We have some evidence that there is activity of these inhibitors in people. There are different markers that we think relate to cancer risk that have been changed by these things. But it will still be several years before we can actually prove one way or the other whether we have lowered the rate of cancer.

What I want to emphasize is that it is feasible now, based on the knowledge from basic science research, to consider and actually design and implement human cancer prevention trials. They are underway. Even while these go on, there are some general guidelines that are prudent for the public to follow. These are lowering fat, increasing fiber, and keeping trim.

Ms. OAKAR. That is very, very helpful.

Dr. Rabson, let me ask you this. In 1963 the NCI in conjunction with the Health Insurance Plan of Greater New York conducted clinical trials relative to determining whether screening did indeed prove successful. Apparently those who were screened had an occurrence of breast cancer death, I believe it is, 23 percent lower than those who were not screened. Am I correct about that figure?

Dr. RABSON. Thirty percent.

Ms. OAKAR. Have you done any followup comparisons to now?

Dr. RABSON. We continue to follow the HIP group. Dr. Greenwald actually is in charge of that followup. I will let him tell you what we do know now about it.

Dr. GREENWALD. First of all, in that study, which was a very well-designed study of 60,000 women, there is a 10- to 14-year-old followup. The benefit is clear, a 30 percent reduction in death.

Ms. OAKAR. For those who have a screening.

Dr. GREENWALD. For those who have the screening.

Ms. OAKAR. Meaning a mammography, that sort of thing.

Dr. GREENWALD. Plus the physician exam.

Ms. OAKAR. A physician exam, and so on.

Dr. GREENWALD. We, together with the American Cancer Society then did a very large demonstration project. Starting in 1973, 280,000 women had a mammography plus physical exam, at a cost of $60 million. We have done a very long-term demonstration project. This provided supportive evidence that the HIP finding was indeed true. There is further confirmation from another trial much like the HIP study, done in Sweden, and two small studies of communities in the Netherlands. So, we have very good confirmation that it is possible to achieve a reduction in breast cancer mortality through screening.

Ms. OAKAR. Let me ask you then, based on that, because I have been so complimentary, you know I have to give you a little shot here and there. Based on the fact that this is successful, why are only three of the grants, of the 3,000 contracts related to breast cancer detection?

Dr. GREENWALD. I think that you have to consider that we now are at the point where we know we have a technology that works. The main need here is application of this knowledge. There is a tremendous amount of other research going on related to breast cancer.

Ms. OAKAR. But let me ask you this, though——

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Dr. GREENWALD. Maybe I should tell you what we are doing to follow up.

Ms. OAKAR [continuing]. All right.

Dr. GREENWALD. In other words, more research on mammography per se, unless it's directed to how to get it applied and adopted across the country, may not merit more research money. In addition, the resources that we expend to try to bring society toward the adoption are more related to our office of cancer communications programs, which have put out hundreds of thousands of pieces of literature, and to our cancer control program. There are 20 or so specific booklets on different aspects of breast cancer that are up to date. We have a cancer information service, which is a telephone hot line you can call.

Ms. OAKAR. In other words, you are saying—because I was going to be critical of the lack—you've got all this great knowledge and sometimes, you know, it's easy to take it for granted. But a lot of people don't really know.

Dr. GREENWALD. That's right.

Ms. OAKAR. So my question is, what are you doing to get this information out?

Dr. GREENWALD. That's the point. We have to look at some balance between our basic research emphasis, which are the grants, and research on how well you use that information—how you help to educate the public and the professionals about it. These are different parts of our budget, so if you just look at the research projects, you might miss the crucially important emphasis on control and on prevention and on dissemination.

Now, one part of the dissemination is a cancer prevention awareness program that is conducted with wide media coverage. It is directed at specific groups like blacks, Hispanics, women's groups, certain working groups.

A second part of it is a cancer communications network, where there is public information located at cancer centers that cover the entire United States. In this program, which started in 1976, there have been over two million phone calls about 26 percent of which relate to breast cancer.

Ms. OAKAR. Why don't you give the public—you'll kill me, but why don't you give the American people the phone number they could call?

Dr. GREENWALD. It's 1-800-4-CANCER. You just dial 1-800, the number 4, CANCER.

Ms. OAKAR. And they can get information and find out how they can get pamphlets.

Dr. GREENWALD. Anything they want. A lot of people call about referral or what they should do. A lot call for information.

Ms. OAKAR. If you run out of funds for those pamphlets, and so on, then you tell us about it and we'll see if we can do something about it.

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Dr. GREENWALD. Let me say one more thing about the adoption of screening. A lot of your testimony had to do with why this proven technology isn't used more widely. And we agree. There's a problem. The National Cancer Institute has set a goal for the year 2000. On this specific question about 45 percent of physicians now do physical exams on the breasts. We are hoping to get it up to 80 percent. Mammography is only done on about 15 percent of women who might benefit.

Ms. OAKAR. Only 15 percent of the women in the country get a mammography?

Dr. GREENWALD. Yes; now, we think to overcome that, screening will have to be built into the usual practice of medicine. That's No. 1. There has to be a way to build it into the usual practice of medicine.

Ms. OAKAR. You know, why don't we do this? Why is it so expensive? It's just awful.

Dr. GREENWALD. I don't know. When you ask a woman why she doesn't have a mammography, based on a Saturday Evening Post survey of thousands of women, their most common response was, "The physician didn't recommend that I have it." If you ask the physicians, their most common response is to refer to the barriers of reimbursement, which are there. I think Dr. Strax and others have talked about what the levels of actual cost might be. I think that type of program is very helpful. It can reach large groups very efficiently. But we also have to build into the usual practice of medicine the idea that screening is part of standard medical practice.

Ms. OAKAR. Is the AMA behind—is this one of their goals, behind screening——

Dr. GREENWALD. The AMA has actually been quite helpful.

Ms. OAKAR [continuing]. Do they encourage their doctors to build that little amount in? The catastrophe costs so much more. I mean, if you have breast cancer—we had a doctor here, a very able witness to the expense of failure.

Dr. GREENWALD. The AMA and other professional societies as well as the American Cancer Society, NCI, are pretty much in agreement on the basic guidelines, the areas where we do have evidence of efficacy. But there is a problem of assuring broad applications, assuring broad availability.

Ms. OAKAR. You know, I have introduced some legislation relative to folding it in under a Medicare program, because this does affect—breast cancer and other forms of cancer do affect older Americans to large proportions. And I think that that prevention would ultimately save the Medicare trust fund a tremendous amount of money, because they will pay for the surgery and all that sort of thing but they won't pay for a mammogram. Does that make sense? It's like the fact that Medicare pays for a blood pressure check only after you prove you have high blood pressure. I mean, we are not reforming very well.

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Senator Pepper has an idea that I certainly endorse that would introduce a community based cancer screening provided by the Federal Government in conjunction with the National Cancer Institute for, I guess related to your research centers, as a beginning 20 comprehensive cancer centers around the country. So, the Government would be involved in this activity. Is that something you think would be a good idea?

Dr. GREENWALD. I think personally that we would have to give a lot of thought to provision of services versus research on how to ensure that the services are available throughout the Nation. I think we have to look at some of the details with you.

It certainly is reasonable to expect our cancer centers to be very much involved in research on cancer detection and providing some services to their own localities.

Ms. OAKAR. I am proud of the fact that, being from Cleveland, we have a great network among places such as Cleveland Clinic. Dr. Crile 25 years ago was called a radical because he didn't believe in radical mastectomies as opposed to more mild forms of surgery, and now he is very much in vogue. He believes that we ought to have screening centers around the country. For $10 or something a woman could get a mammography.

Dr. GREENWALD. It is very helpful to have that, as I think Dr. Strax demonstrated, as well as others. I do not think it will replace completely the need to build into the usual practice of medicine screening, because that is where most of the people of the country are going to be seen. And we need some effort on how to figure out what the rewards and incentives are for physicians and hospitals and medical practices to use mammography, so and that when women go to the doctor they are offered the screening exam.

Ms. OAKAR. It seems reasonable to me. I can't understand why we can't, in a sophisticated society, have that folded in. Maybe through this hearing we have raised the level of awareness.

This is Breast Cancer Awareness Week. We hope NCI at one point will have a special division devoted exclusively to breast cancer. I know you mentioned, Doctor, that your research on cancer cells affects all forms of cancer, but this is by and large the No. 1 killer of women, half the population. We really need you to try to help us in our efforts.

What we are trying to say in Breast Cancer Awareness Week is that women should not be afraid of finding out or not finding out what they have, that they ought to get those physicals and mammographies. They don't have to do it all often. They do it once a year, I guess, after you're age 40 or more. Beyond that, there have been tremendous efforts made to improve the type of surgery that is performed and the options that are given. Women ought to make sure they are knowledgeable and ask a lot of questions before they go into their surgery.

We are also trying to say that, beside prevention, we want a cure for cancer. We as Government officials ought to be doing more in helping your efforts.

So, that is what the hearing is all about. We want to thank everybody who has participated.

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At this point in time I want to thank my chairman, Senator Pepper, who was here for a good part of the hearing.

We have a lot of additional statements that we are going to put in the record. We are going to hold up our hearing record for a few days. So, if anybody has some statements they want to submit for our record, we would be happy to have them.

We have another fine available booklet, probably more for the libraries than for the general public, on our earlier hearing in 1984, which took a different slant on things but was also very interesting, I found.

Thank you very, very much. At this point the hearing is adjourned.

[Whereupon, at 1:40 p.m., the hearing was adjourned.]

[The additional material referred to, follows:]

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APPENDIX 1

SUBMITTED FOR THE RECORD BY CHAIRWOMAN MARY ROSE OAKAR

DEPARTMENT OF HELATH & HUMAN SERVICES,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville MD, August 21, 1984.

Hon. MARY ROSE OAKAR,
House of Representatives,
Washington, DC.

DEAR MS. OAKAR: We are pleased to furnish you the information that Ms. Millie Vinicor, of your staff, requested from the Food and Drug Administration's (FDA) Center for Devices and Radiological Health, regarding regulations pertaining to medical radiation; rather, we regulate the manufacturers of radiation-emitting devices to ensure that these devices are safe and effective for human use.

Enclosed are the regulations for the administration and enforcement of the "Radiation Control for Health and Safety Act of 1968," as well as a copy of the Act itself. The regulation start on Page 306 of Title 21, Code of Federal Regulations.

Also enclosed is a copy of Public Law 97-35, the "Consumer-Patient Radiation Health and Safety Act of 1981." Although FDA has issued no regulations under this Act, we have developed and implemented a number of voluntary programs under section 982 of this statute. An example of such efforts is a nationwide program we have conducted to reduce unnecessary radiation exposure during mammography. Details of that program are explained in the document entitled, BREAST EXPOSURE: NATIONWIDE TRENDS. One of the major provisions if this Act was the development of standards for the certification of persons who perform radiologic procedures. Responsibility for the development of those standards was given to the Department's Health Resources and Services Administration. You may contact Dr. William Brooks at the address shown on the copy of the Act for further information.

Other Federal agencies, such as the Veterans Administration, the Department of Defense, and the Health Care Financing Administration, may also have regulations that are of interest to you. You may wish to contact them for further information.

I hope the enclosed information is helpful to you. If we can be of any further assistance, please let me know.

Sincerely yours,

ROBERT C. WETHERELL, Jr.,
Associate Commissioner for Legislation and Information.

Five enclosures: CFR § 1020.30; The Act; Public Law 97-35; Breast Exposure: Nationwide Trends; and FR 7/12/83.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, *October 5, 1983.*

To: Commissioner of Food and Drugs.
From: Assistant Secretary for Health.
Subject: Delegation of Authority Under the Consumer-Patient Radiation Health and Safety Act of 1981.

On July 28, 1983 the Secretary of Health and Human Services delegated to the Assistant Secretary for Health, with authority to redelegate, all authorities vested in the Secretary under Title IX, Subtitle I, Consumer-Patient Radiation Health and Safety Act of 1981, of Public Law 97-35, Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 10001 et seq.), as amended. The delegation excluded the authority to promulgate regulations, submit reports to the Congress, and transmit the model statute to the States. I hereby delegate to the Commissioner of Food and Drugs, with authority to redelegate, ail authorities delegated to the Assistant Secretary for Health

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under sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981, as amended, (42 U.S.C. 10007 and 10008) excluding the authority to promulgate regulations and submit reports to the Congress. The authority delegated under section 983 of the Act may only be exercised as it relates to functions assigned to the Food and Drug Administration.

This delegation is effective on date of signature.

EDWARD N. BRANDT, Jr., M.D.

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The contact person for inquiries regarding the Consumer-Patient Radiation Health and Safety Act should be addressed to:

Dr. William Brooks
Health Resources and Services Administration
8-95 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

inserting in lieu thereof [illegible] administration of drug abuse prevention activities".

1191. (f) Section 501 is amended by striking out "Health, Education, and Welfare" and inserting in lieu thereof "Health and Human Services".

Subtitle I—Consumer-Patient Radiation Health and Safety Act of 1981

SHORT TITLE

10001 SEC. 975. This subtitle may be cited as the "Consumer-Patient Radiation Health and Safety Act of 1981".

STATEMENT OF FINDINGS

10001 SEC. 976. The Congress finds that—

(1) it is in the interest of public health and safety to minimize unnecessary exposure to potentially hazardous radiation due to medical and dental radiologic procedures;

(2) it is in the interest of public health and safety to have a continuing supply of adequately educated persons and appropriate accreditation and certification programs administered by State governments;

(3) the protection of the public health and safety from unnecessary exposure to potentially hazardous radiation due to medical and dental radiologic procedures and the assurance of efficacious procedures are the responsibility of State and Federal governments;

(4) persons who administer radiologic procedures, including procedures at Federal facilities, should be required to demonstrate competence by reason of education, training, and experience; and

(5) the administration of radiologic procedures and the effect on individuals of such procedures have a substantial and direct effect upon United States interstate commerce.

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STATEMENT OF PURPOSE

SEC. 977. It is the purpose of this subtitle to— 42 USC 10002.

(1) provide for the establishment of minimum standards by the Federal Government for the accreditation of education programs for persons who administer radiologic procedures and for the certification of such persons; and

(2) insure that medical and dental radiologic procedures are consistent with rigorous safety precautions and standards.

DEFINITIONS

SEC. 978. Unless otherwise expressly provided, for purposes of this subtitle, the term— 42 USC 10003.

(1) "radiation" means ionizing and nonionizing radiation in amounts beyond normal background levels from sources such as medical and dental radiologic procedures;

(2) "radiologic procedure" means any procedure or article intended for use in—

(A) the diagnosis of disease or other medical or dental conditions in humans (including diagnostic X-rays or nuclear medicine procedures); or

(B) the cure, mitigation, treatment, or prevention of disease in humans;

that achieves its intended purpose through the emission of radiation;

(3) "radiologic equipment" means any radiation electronic product which emits or detects radiation and which is used or intended for use to—

(A) diagnose disease or other medical or dental conditions (including diagnostic X-ray equipment); or

(B) cure, mitigate, treat, or prevent disease in humans,

that achieves its intended purpose through the emission or detection of radiation;

(4) "practitioner" means any licensed doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic, who prescribes radiologic procedures for other persons;

(5) "persons who administer radiologic procedures" means any person, other than a practitioner, who intentionally administers radiation to other persons for medical purposes, and includes medical radiologic technologists (including dental hygienists and assistants), radiation therapy technologists, and nuclear medicine technologists;

(6) "Secretary" means the Secretary of Health and Human Services; and

(7) "State" means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

PROMULGATION OF STANDARDS

SEC. 979. (a) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the accreditation of educa- 42 USC 10004.

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tional programs to train individuals to perform radiologic procedures. Such standards shall distinguish between programs for the education of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall not be applicable to educational programs for practitioners.

(b) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, interested agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the certification of persons who administer radiologic procedures. Such standards shall distinguish between certification of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall include minimum certification criteria for individuals with regard to accredited education, practical experience, successful passage of required examinations, and such other criteria as the Secretary shall deem necessary for the adequate qualification of individuals to administer radiologic procedures. Such standards shall not apply to practitioners.

MODEL STATUTE

10905 SEC. 980. In order to encourage the administration of accreditation and certification programs by the States, the Secretary shall prepare and transmit to the States a model statute for radiologic procedure safety. Such model statute shall provide that—

(1) it shall be unlawful in a State for individuals to perform radiologic procedures unless such individuals are certified by the State to perform such procedures; and

(2) any educational requirements for certification of individuals to perform radiologic procedures shall be limited to educational programs accredited by the State.

COMPLIANCE

10906 SEC. 981. (a) The Secretary shall take all actions consistent with law to effectuate the purposes of this subtitle.

(b) A State may utilize an accreditation or certification program administered by a private entity if—

(1) such State delegates the administration of the State accreditation or certification program to such private entity;

(2) such program is approved by the State; and

(3) such program is consistent with the minimum Federal standards promulgated under this subtitle for such program.

(c) Absent compliance by the States with the provisions of this subtitle within three years after the date of enactment of this Act, the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the States' compliance with this subtitle.

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(d) The Secretary shall be responsible for continued monitoring of compliance by the States with the applicable provisions of this subtitle and shall report to the Senate and the House of Representatives by January 1, 1982, and January 1 of each succeeding year the status of the States' compliance with the purposes of this subtitle. Report to Congress

(e) Notwithstanding any other provision of this section, in the case of a State which has, prior to the effective date of standards and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle.

FEDERAL RADIATION GUIDELINES

SEC. 982. The Secretary shall, in conjunction with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, promulgate Federal radiation guidelines with respect to radiologic procedures. Such guidelines shall— 42 USC 10007

(1) determine the level of radiation exposure due to radiologic procedures which is unnecessary and specify the techniques, procedures, and methods to minimize such unnecessary exposure;

(2) provide for the elimination of the need for retakes of diagnostic radiologic procedures;

(3) provide for the elimination of unproductive screening programs;

(4) provide for the optimum diagnostic information with minimum radiologic exposure; and

(5) include the therapeutic application of radiation to individuals in the treatment of disease, including nuclear medicine applications.

APPLICABILITY TO FEDERAL AGENCIES

SEC. 983. (a) Except as provided in subsection (b), each department, agency, and instrumentality of the executive branch of the Federal Government shall comply with standards promulgated pursuant to this subtitle. 42 USC 10008

(b)(1) The Administrator of Veterans' Affairs, through the Chief Medical Director of the Veterans' Administration, shall, to the maximum extent feasible consistent with the responsibilities of such Administrator and Chief Medical Director under subtitle 38, United States Code, prescribe regulations making the standards promulgated pursuant to this subtitle applicable to the provision of radiologic procedures in facilities over which the Administrator has jurisdiction. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall consult with the Secretary in order to achieve the maximum possible coordination of the regulations, standards, and guidelines, and the implementation thereof, which the Secretary and the Administrator prescribe under this subtitle. Regulations

38 USC 101 *et seq*

(2) Not later than 180 days after standards are promulgated by the Secretary pursuant to this subtitle, the Administrator of Veterans' Report to congressional committees

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Affairs shall submit to the appropriate committees of Congress a full report with respect to the regulations (including guidelines, policies, and procedures thereunder) prescribed pursuant to paragraph (1) of this subsection. Such report shall include—

(A) an explanation of any inconsistency between standards made applicable by such regulations and the standards promulgated by the Secretary pursuant to this subtitle;

(B) an account of the extent, substance, and results of consultations with the Secretary respecting the prescription and implementation of regulations by the Administrator; and

(C) such recommendations for legislation and administrative action as the Administrator determines are necessary and desirable.

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(3) The Administrator of Veterans' Affairs shall publish the report required by paragraph (2) in the Federal Register.

Subtitle J—Orderly Closure, Transfer, and Financial Self-Sufficiency of Public Health Service Hospitals and Clinics

FINDINGS AND PURPOSES

SE' 248b

SEC. 985. (a) Congress finds that—

(1) because of national budgetary considerations, it has become necessary to terminate Federal appropriations for Public Health Service hospitals and clinics,

(2) with proper planning and coordination, some of these hospitals and clinics could be transferred to State, local, or private control or become financially self-sufficient and continue to provide effective and efficient health care to individuals in the areas in which they are located,

(3) a precipitous closure of these hospitals and clinics will preclude the possibility of such orderly transfer to entities which are willing and able to take over operations at such facilities and will cause unnecessary and costly hardships on the patients and staffs at such facilities and on the communities in which the facilities are located, and

(4) it is in the national interest, consistent with sound budgetary considerations, to assist in the orderly and prompt transfer of such operations to State, local, or private operation or in the achievement of financial self-sufficiency where feasible.

(b) The purposes of this subtitle are—

(1) to provide for the prompt and orderly closure by October 31, 1981, of Public Health Service hospitals and clinics which cannot reasonably be transferred to State, local, or private operation or become financially self-sufficient and for the transfer or achievement of financial self-sufficiency by September 30, 1982, of those hospitals and clinics which can be so transferred or which can achieve such financial self-sufficiency, and

(2) to provide for transitional assistance for merchant seamen whose entitlement to receive free care through Public Health Service hospitals and clinics is repealed and who are hospitalized at the end of fiscal year 1981 and require continuing hospitalization.

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ELIMINATION OF MERCHANT MARINE ENTITLEMENT TO HEALTH SERVICES

SEC. 986. (a) Subsection (h) of section 2 and subsections (a) and (b) of section 322 of the Public Health Service Act are repealed. 42 USC 201, 249

(b)(1) Section 322(e) of such Act is amended—

(A) by striking out "entitled to care and treatment under subsection (a) of this section and persons"; and

(B) by striking out "subsection (c)" and inserting in lieu thereof "subsection (a)".

(2) Subsections (c), (d), and (e) of section 322 of such Act are redesignated as subsections (a), (b), and (c), respectively.

(3) The section heading for section 322 of such Act is amended by striking out "SEAMEN" and inserting in lieu thereof "PERSONS UNDER QUARANTINE".

(4) Section 332(a)(2)(C) of such Act is amended by striking out "seamen" and inserting in lieu thereof "persons under quarantine". 42 USC 254e

(c) The amendments and repeals made by this section shall take effect on October 1, 1981. Effective date 42 USC 249 note

PROPOSALS FOR TRANSFER OR FINANCIAL SELF-SUFFICIENCY OF PUBLIC HEALTH SERVICE HOSPITALS AND CLINICS

SEC. 987. (a) The Secretary of Health and Human Services (hereinafter in this subtitle referred to as the "Secretary") shall, in accordance with this section and notwithstanding section 818 of Public Law 93-155, provide for the closure, transfer, or financial self-sufficiency of all hospitals and other stations of the Public Health Service (hereinafter in this subtitle referred to as the "Service") not later than September 30, 1982. 42 USC 248b 42 USC 248a

(b) Not later than July 1, 1981, the Secretary shall notify each Service hospital and other station, and the chief executive officer of each State and of each locality in which such a hospital or other station is located, that the Secretary will accept proposals for the transfer of each such hospital and station from the Service to a public (including Federal) or nonprofit private entity or for the achievement of financial self-sufficiency of each such hospital and station not later than September 30, 1982. No such proposal shall be considered by the Secretary if it is submitted later than September 1, 1981.

(c) The Secretary shall evaluate promptly each proposal submitted under subsection (b) with respect to a hospital or other station and determine, not later than September 30, 1981, whether or not under such proposal the hospital or station—

(1) will be maintained as a general health care facility providing a range of services to the population within its service area,

(2) will continue to make services available to existing patient populations, and

(3) has a reasonable expectation of financial viability and, in the case of a hospital or station that is not proposed to be transferred, of financial self-sufficiency.

Paragraph (1) shall not apply in the case of a proposal for the transfer of a discrete, minor, freestanding part of a hospital or station to a local public entity for the purpose of continuing the provision of services to refugees.

(d)(1) If the Secretary determines that a proposal for a hospital or other station does not meet the standards of subsection (c) or if there is no proposal submitted under subsection (b) with respect to a hospital or other station, the Secretary shall provide for the closure of the hospital or station by not later than October 31, 1981.

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[From the Washington Star, July 11, 1978]

Responsibility for Radiation Hazard Splintered

(By Cristine Russell)

Everybody seems to acknowledge there's a problem but nobody knows quite what to do about it.

Congressional committees, the White House, outside scientific experts, public interest groups, and even the federal agencies involved are concerned about the adequacy of the government's effort to control public exposure to low levels of radiation from a variety of sources.

A recent Senate Governmental Affairs Committee study on federal regulation of radiation health and safety summed up the problem this way:

"Responsibility is scattered and uneven, resulting in jurisdictional disputes and regulatory confusion. Too many agencies are charged with administering too many laws. And nobody has the clear ability to overview the total situation, or the power to guide and coordinate that dispersed authority.

"As a result, coordination is not always systematic, the extent of the risks is not fully understood, and some potentially significant hazards are not subject to any federal controls at all. The field of radiation safety shows many deficiencies which typically mark a piecemeal approach to federal regulation."

The committee's report noted that "every indication points to increased medical, military, industrial, consumer and energy production use of radioactive materials and sources in the future," with a proportionately increased risk to public health and safety.

Radiation exposure has been associated with an added chance of contracting cancer, as well as the danger of possible genetic defects in future generations.

Yet the responsibility for radiation regulation and research is scattered in at least eight federal departments, two independent commissions and many other government agencies of the national level.

These include the departments of Agriculture, Commerce, Defense, Energy, Health Education and Welfare, Labor, Transportation, Treasury, the Nuclear Regulatory Commission and the Consumer Product Safety Commission, as well as the Environmental Protection Agency, Veterans Administration, and U.S. Postal Service.

The fact that "there are literally dozens of federal departments, agencies, bureaus, commissions, boards or other entities involved in protecting the public from the hazards of radiation protection" concerned the Senate committee, which concluded that "what is needed is a central focus in the federal government to assure that radiation exposure, whatever its source or application, is subject to coordinated federal controls and programs."

Equally critical comments have come from others who have looked at the status of the federal radiation protection program, with the focus largely on the four agencies with the lion's share of activities:

Department of Energy. DOE has the responsibility to encourage the peaceful development of nuclear power "to the maximum extent consistent with the common defense and security and with the health and safety of the public." In addition, it is responsible for the country's nuclear weapons.

The department inherited the functions of the Energy Research and Development Administration, which in turn took over many of the duties of the old Atomic Energy Commission.

This is part of the problem, contends Rep. Paul Rogers, D-Fla., who expressed concern, in an interview, that "we haven't had much fresh thinking on the matter. The whole approach to low-level radiation is one of avoidance, maybe even studied avoidance, an unwillingness to face facts and an effort to even prevent the facts from being developed. There's some danger from low-level radiation and we ought to find out what it is and how to handle it."

Hearings by his Health and Environment Subcommittee earlier this year investigated DOE's decision to discontinue funding of the controversial study by University of Pittsburgh researcher Dr. Thomas Mancuso, which suggested an increased cancer risk to plutonium workers after years of exposure to low levels of radiation previously considered safe.

Based on the committee's findings, Rogers recently wrote to DOE Secretary James Schlesinger complaining about the "serious management deficiencies" in the department's radiation health effects research program and questioning whether the present authority for health research should remain in the department given the mission regarding the environmental group's petition. Sources indicated that a

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public hearing on the controversial issue will be recommended but that the staff is likely to advise against a tenfold reduction in the occupational limit.

Robert Minogue, director of NRC's Office of Standards Development, feels that reducing the limit in that fashion might in fact lead to an increase in overall exposure. This seeming contradiction, he said, stems from the fact that the nuclear industry might then employ more people to do the "dirtier" maintenance work involving higher exposures, thereby exposing greater numbers of individuals to the risk.

"It's a debate over what's the best regulatory approach," said Minogue. He's leaning in the direction of imposing an "as low as reasonably achievable" limit, with the adoption of stronger enforcement measures.

Today another consumer organization, the Nader-backed Health Research Group, is issuing a "worker's guide to unsafe atomic power plants" supporting the push for a lower occupational standard. It's asking that the regulatory power for nuclear workers' health be transferred to the Labor Department's Occupational Safety and Health Administration, according to director Sidney Wolfe.

Food and Drug Administration. While the FDA's Bureau of Radiological Health has authority to regulate the manufacture of radiation-emitting machines (setting performance standards for commercial products, such as airport baggage inspection devices, in addition to those for medical X-ray equipment), it has less control over equipment use by the technologists who administer the X-rays or the doctors who order them in the first place.

While the medical area offers the greatest potential for controlling unnecessary exposure, some critics feel that the government has been too timid in intruding upon the doctors' traditional domain.

John Villforth, head of the bureau, acknowledged in an interview that, in hindsight, the agency has been slow in tackling medical X-ray use problems—"We felt it was so much an individual thing between the doctor and his patient"—but that a stepped-up effort is under way to provide guidelines for the ordering of common diagnostic X-ray procedures.

"We're waking up to the fact that we can also have a greater influence" in helping consumers "participate in the decision-making," said Villforth.

He admitted that cumulative medical exposure was uncontrolled and that individual patients, faced with a variety of medical problems, could perhaps the broadest across-the-board authority to oversee the public's exposure to radiation. It received authority to advise the president on radiation safety questions—this was transferred from an abolished Cabinet-level Federal Radiation Council—as well as the ability to establish general environmental standards for radioactive materials.

But the agency's authority has been challenged and its few attempts to take any action have stimulated vigorous institutional struggles with the other agencies involved.

For example, it has had a running argument with FDA over guidelines for federal facilities in the medical area. When it formed an "interagency working group on medical radiation" more than three years ago, the FDA declined to join the group. A compromise was finally reached and guidelines to federal agencies for diagnostic X-rays, signed by President Carter, were issued earlier this year.

When EPA attempted to tread into regulation of the nuclear fuel cycle, it ran into a roadblock with the Atomic Energy Commission—it took some six years to develop a modified standard acceptable to the parties involved.

An indictment of EPA's radiation program was issued by the General Accounting Office in January in a report which concluded that it has been plagued by "jurisdictional challenges to the agency's authority, staffing and funding reductions, an inability to retain competent professionals, limited cooperation with other agencies and research groups and low priority placed on radiation protection."

The GAO warned that "without extensive changes, the Environmental Protection Agency will continue to be limited in its ability to protect public health and the environment from radiation dangers." The EPA, says program director Dr. W.D. Rowe, would "welcome" having its role "clarified."

Whether EPA or some other agency should be given a strengthened "lead agency" role, whether a more prominent White House coordinating council with "teeth" to act or an independent commission should be set up is the subject of hearings by a House Government Operations subcommittee.

The Senate Governmental Affairs Committee is readying recommendations, based upon responses to its report, as will the Senate and House Commerce committees, which have had extensive hearings over the past year.

In the meantime, the status of radiation research and regulation is undergoing a massive self-examination by the executive branch with * * *.

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Based on the committee's findings, Rogers recently wrote to DOE Secretary James Schlesinger complaining about the "serious management deficiencies" in the department's radiation health effects research program and questioning whether the present authority for health research should remain in the department, given the "potential for conflict of interest."

Rogers' concerns coincide to some extent with the more outspoken charges for critics such as the Environmental Policy Center's Robert Alvarez, who has accused DOE of a "cover-up."

Dr. James Liverman, DOE's assistant secretary for environment, has repeatedly defended the handling of the Mancuso study on several grounds. The matter has been under investigation by the department's inspector general.

Nuclear Regulatory Commission. When the Atomic Energy Commission was split in two, the NRC received the primary authority for regulating nuclear power—the construction, licensing and operation of facilities as well as the safe storage, handling and transportation of nuclear materials.

Based upon earlier recommendations by scientific bodies, the NRC set exposure limits in nuclear facilities which are now being challenged in light of recent health finding of risks at lower levels.

The Natural Resources Defense Council, a public interest firm, has had a petition pending with the NRC for more than two years which contends that the occupational exposure standards should be lowered by a factor of 10. NRC staff scientist Dr. Arthur Tamplin, a biophysicist formerly with the AEC, believes better overall standards for general public exposure from all radiation sources also must be developed.

The NRC staff is in the process of preparing a final paper for the com- * * *.

"We're waking up to the fact that we can also have a greater influence" in helping consumers "participate in the decision-making," said Villforth.

He admitted that cumulative medical exposure was uncontrolled and that individual patients, faced with a variety of medical problems, could be getting diagnostic radiation exposures in excess of what workers receive.

But while voicing the philosophy that any unnecessary exposure should be avoided, Villforth cautioned against "overreacting. I dread very much someone needing an X-ray and having somebody say he shouldn't get it. If it's needed, it's needed."

Environmental Protection Agency. The creation of EPA in 1970 gave it * * * as will the Senate and House Commerce committees, which have had extensive hearings over the past year.

In the meantime, the status of radiation research and regulation is undergoing a massive self-examination by the executive branch, with the Department of Health, Education and Welfare coordinating the goverment-wide effort. A report to the White House is expected this fall.

Whatever the findings of these various groups, they will undoubtedly touch off a new set of "turf battles," legislative deliberations and public debate which may continue for years to come. The problems of fragmentation and divided responsibility in protecting the public from radiation risks are not likely to be solved in the near-term.

WHAT YOU CAN DO FOR YOURSELF

While government agencies struggle over how to regulate radiation exposure, consumers can take their own actions to keep their personal exposure down. Since medical procedures constitute more than 90 percent of man-made exposure, avoiding unnecessary X-rays could make a major contribution toward reducing potential risks. Here are some tips offered by public health experts to help patients participate in the "risk-benefit" decision-making process:

If your doctor or dentist orders an X-ray, ask for an explanation of how it will help with your diagnosis. Generally speaking, X-rays should not be undertaken without an indication of possible benefit.

Let your doctor know about any similar X-ray exams you may have had. Keep a record in your wallet for an easy reference list of past exams (the Food and Drug Administration has printed cards for this purpose).

For protection of the reproductive organs, ask if lead gonad shielding can be used when an X-ray is being given.

Women should let their doctors know if they're pregnant before having an X-ray. If so, those in the abdominal region should generally be avoided unless a serious need exists.

Question the need for routine or screening exams as part of annual checkups or employment requirements. In terms of dental exams, federal guidelines suggest that

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they should not be routinely used without prior examination of the teeth by the dentist.

Inquire about when the X-ray facilities have been inspected.

Finally, don't insist on getting an X-ray if your doctor isn't ready to order one.

[From Medical World News, Oct. 12, 1981]

Feds Push Licensing of X-Ray Technicians

Washington.—Congress has ordered HHS to devise minimum standards for licensing radiology technicians and to encourage states to adopt them as law. The directive caps a 12-year crusade by Sen. Jennings Randolph (D–W. Va.), who's worried about the uncredentialed thousands operating x-ray and other irradiating equipment for physicians and dentists.

The licensing plan, which quietly became law as part of Congress' budget bill, isn't as objectionable to the AMA and the American Dental Association as an earlier Randolph proposal for mandatory state licensing. But, after three years of the voluntary program, HHS must report to Congress on the advisability of requiring states to use the model standards.

Of some 185,000 technicians operating diagnostic x-ray, nuclear scanning, and radiation-therapy equipment for doctors, about half are credentialed by the American Registry of Radiologic Technologists (ARRT) or other voluntary certifying bodies, says Randolph's health staffer, Thomas H. Altmeyer. Eleven states and Puerto Rico license technicians, usually by requiring such certification.

Noting that the FDA's Bureau of Radiological Health (BRH) attributes 2,000 to 4,000 annual cancer deaths to diagnostic or therapeutic radiation, Altmeyer says "its reasonable to assume incompetence by some technicians contributes to that rate." The bulk of uncertified technicians, he adds, work in private offices.

The American Society of Radiologic Technologists, a Randolph ally that represents some 20,000 certified equipment operators, wants mandatory standards patterned on those of the relatively tough ARRT. The registry—governed by both technicians and radiologists—certifies those who've completed at least two years of training in an AMA-approved program and who've passed a written test. Michael D. Thayer, the society's assistant director, says an ARRT-certified professional knows a lot more than his machinery and the best position for the glenoid fossa. "He is schooled in aseptic technique and can take a history that will help a radiologist interpret the films."

So what's bothering the AMA? "It's been suggested," says Thayer, "that they're opposed to licensing because a certified technologist can ask a higher salary."

Where 45,000 Doctors Can't Deliver X-Rays

Sacramento.—Boldest of the states that license or certify operators of diagnostic and therapeutic x ray equipment, California makes no exception for physicians.

Under a law that took effect in 1972, all physicians except boarded radiologists are prohibited from operating such equipment unless they earn a certificate by passing the state's two-hour written radiation-safety exam. Only some 9,000 of the state's 54,000 physicians have a certificate, says Val Zemitis, certification director for California's division of radiological health here. The test failure rate runs between 8% and 20%, he adds.

The same law, however, makes a non-physician travel a longer route before winning the right to push an x-ray button. The state's 12,000 "fully certified technologists"—most can take the full array of diagnostic x rays—qualified by completing at least two years of AMA-accredited training and getting a California-set passing grade on the test of the American Registry of Radiologic Technologists. A "limited permit technician"—who may, for instance, only have the right to do a chest x-ray—also takes the test, but needs less training and can get it, unaccredited, in a physician's office.

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APPENDIX 2

COLLECTION OF ARTICLES AND LETTERS ON TREATMENT COSTS VERSUS SCREENING COSTS—SUBMITTED BY ROSE KUSHNER

[From Oncology Times, May 1984]

THE MEDICAL COSTS FOR CANCER EXCEEDED $10 BILLION IN 1980

NEW YORK CITY.—The current cost of medical care for cancer in the United States is more than $10 billion dollars annually, accounting for about five percent of all medical care expenditures, according to data from the U.S. National Center for Health Statistics. Thomas A. Hodgson, PhD, chief economist of the Center's Office of Analysis and Epidemiology, reported on the economic burden of cancer at the American Cancer Society's Fourth National Conference on Human Values and Cancer held here in March.

In 1980, neoplasms of all types required 26 million days of care in shortstay hospitals and 27 million visits to physicians for diagnosis and treatment, Dr. Hodgson told Oncology Times, explaining that 1980 was the latest year for which data were available. The use of medical care for these neoplasms resulted in expenditures for personal health care in 1980 estimated at $13.6 billion, with at least $10.3 billion (76%) for persons with malignant neoplasms. If the $469 billion spent in nursing homes, which could not be allocated by site, is included, the proportion spent for cancers is increased to 79 percent.

Hospitals care accounted for $9.1 billion, which was two-thirds of the total spent for neoplasms, he said. Services for physicians required another $3.2 billion (23% of the total); lesser amounts were spent for nursing home care ($469 million), drugs ($677 million), and other professional services ($184 million).

Cancers of the digestive organs and peritoneium were the most expensive of the sites studied ($2 billion). Next were cancers of the trachea, lung, and bronchus ($1.6 billion) and breast ($1.3 billion). Benign neoplasms were relatively expensive, accounting for $2.8 billion, or 21 percent of the expenditure for all neoplasms.

RELATIVE COMPARISONS

Medical Care expenditures for neoplasms were higher for females than for males (almost $8 billion versus $5.6 billion), but most of this difference occurred among people younger than 65. For some sites, however, males required higher expenditures: cancers of the digestive organs, trachea, bronchus, and lung.

"Large sums in the billions of dollars in isolation have little meaning for most of us," Dr. Hodgson said. "To put the numbers in perspective, it can be shown that medical care for neoplasms cost 15 percent of the amount spent for gasoline and oil, 22 percent of spending for residential energy consumption, two thirds of expenditures on tobacco, and 93 percent of the cost of medical care for heart disease. On the other hand, spending for neoplasms was 18 percent higher than what the nation's consumers spent on legal services, 39 percent more than the amount for higher education, and more than twice the amount spent for admissions to a variety of spectator amusements."

Illness due to cancer prevents people from leading their accustomed productive lives. Morbidity and disability from neoplasms in 1980 resulted in $2.6 billion of output and productivity foregone, as measured by the value in terms of wages and salaries of idled labor and housekeepers. Dr. Hodgson said the largest part of the total ($1 billion, or 40%) occurred among males unable to work. Almost the same amount was estimated for currently employed people who lost time from work.

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INDIRECT COSTS

Indirect costs are the time and output lost or foregone by the patient, family, friends, and others from employment, housekeeping, volunteer activities, and leisure. Additional indirect costs include the time the patient and/or family spends visiting physicians, other health professionals, and hospitalized patients.

Morbidity and mortality from neoplasms in 1980 deprived the nation of seven million person-years of productive activity at an estimated value of $29.6 billion, he reported. "It is important to emphasize, however, that not all of the person-years lost or costs were incurred in 1980. Included in these figures are the years lost and value of productivity foregone in succeeding years as a result of premature mortality in 1980. In order to make meaningful comparisons among amounts occurring in different time periods, the stream of future money values for each individual who died in 1980 was converted to a 1980 present value. These values were then summed over all persons to arrive at a total value of person-years lost from mortality in 1980."

The indirect costs of neoplasms were more than two-thirds of payrolls, wages, and salaries paid to construction workers and three-fourths of the labor cost of instruction in public elementary and secondary schools in the U.S. Costs of neoplasms were 30 percent higher than the total payroll for telephone company employees, and about twice as high as the wages and salaries paid to employees in all eating and drinking places.

The total economic costs of neoplasms, including direct and indirect costs, were estimated at $43.1 billion in 1980, Dr. Hodgson said. "While medical care expenditures have caused concern for some years now, our analysis shows that indirect costs of neoplasms in 1980 were more than double the direct costs. Personal health care expenditures for neoplasms were almost one-third of total costs, morbidity accounted for six percent, and mortality losses were just under 63 percent of all costs." It is important to consider both direct and indirect costs in order to more fully account for the burden of illness and more accurately compare costs of several diseases, he stressed.

RADIATION ONCOLOGY CENTER,
HARPER-GRACE HOSPITALS,
Detroit, MI, June 12, 1984.

Mrs. ROSE KUSHNER,
Kensington, MD.

DEAR ROSE: I am writing in response to your inquiry about some of the most pressing problems facing women who have or are worried about having breast cancer. For the purpose of your presentation before the Select House Committee on Aging on June 28, 1984, I have chosen those problems which, in my opinion, can be solved via the Congress.

The foremost problem, I believe, relates to all cancers; we do not know today's actual costs for curing cancer patients. Knowing this cost is imperative so we can (a) relate our cancer research budget to actual, overall costs of the disease; (b) have a target for reducing these cancer-care costs in the future. My reasons are simple: cancer is a chronic disease that requires large expenditures for detection, diagnosis, treatment, rehabilitation and terminal care. Unless we know all of these costs precisely, we cannot allocate the required proportion of research monies curing patients of cancer requires.

Costs are especially important in the case of breast cancer, because about 80% of all patients are older than age 50. In these women the disease generally grows more slowly and the afflicted women live more years with long term suffering if the cancer recures or is not cured.

I am aware of the fact that Dr. Tom Hodgson of the National Center for Health Statistics has stated that the direct cost of cancer care is $10 billion. While I do not have firm information for refuting his total, I reject the assertion entirely. My reason for this rejection is, again, simple: it is estimated that 20% of all people die of cancer. I believe that the initial costs of concern about cancer is great and that money spent to detect or rule out cancer is not included in the $10 billion total. Nor are terminal-care costs of cancer patients included. Since total health-care expenditures in the United States have been estimated to be greater than $300 billion for 1984, I cannot believe that cancer-care costs would total only $10 billion of this huge sum, if the above expenditures were included.

In addition, the National Center for Health Statistics' numbers do not include the $1 billion spent by the National Cancer Institute or the $200 million by the American Cancer Society or dollars spent by other governmental or voluntary health

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agencies. I also do not believe the Center has a realistic estimate of the costs of care of the dying patient or of the costs of care of people who are receiving out-patient care over a two-to-three year period.

It is my belief that only by a program mandated by the Congress will the actual costs of cancer be established and I think the National Cancer Institute's SEER Program is an excellent mechanism for collecting and analyzing these data.

The reason I think the House Committee on Aging is the ideal forum for discussing this subject is that cancer is the most catastrophic event in the life of an older individual. Developing cancer at a time when their resources and strength may already be threatened make it even more difficult for older persons to cope with this terrible problem.

As I said earlier, breast cancer is especially important because most patients are in the elderly group receiving support for their care with Medicare or Medicaid. The costs to these patients and to their families are great because the disease is relatively slow-growing and therefore more expensive to treat. Breast cancer can consume a women's resources and savings, not to mention those of her family.

My preoccupation with the dollars is not cold-hearted, but is related to the fact that if we are in fact spending $30 billion per year for cancer care costs (direct costs) then the $1 billion in research and development money for the National Cancer Institute is minute, considering today's opportunities for effective and appropriate research. I, again, wish to stress that we are spending too small an amount of money for research on breast cancer in proportion to the effect of the disease on our elder population.

I believe that the Congress could contribute greatly to the solution by mandating a study of the economic costs to the public of the problems of cancer.

Many thanks.

Sincerely,

WILLIAM E. POWERS, M.D.

AMERICAN SOCIETY OF CLINICAL ONCOLOGY,
Chicago, IL, February 1985.

To: ASCO members.
Subject: Position papers.

Enclosed for information, resources and guidance are three (3) position papers prepared by the ASCO Clinical Practice Committee and approved for distribution to the membership by the Board of Directors. They are:

(1) Investigational Drug Therapy Reimbursement
(2) Parenteral Chemotherapeutic Agents
(3) Guidelines for the Use of Current Procedural Terminology (CPT-4) Relating to Chemotherapy Administration

These papers may be reproduced to be shared with your associates and colleagues providing they carry the ASCO identity.

These position papers are provided as a membership service of ASCO.

CLINICAL PRACTICE COMMITTEE.

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INVESTIGATIONAL DRUG THERAPY REIMBURSEMENT
POSITION STATEMENT OF
THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

DAVID PRAGER, M.D.

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INVESTIGATIONAL DRUG THERAPY REIMBURSEMENT

Investigational drugs are generally divided into three groups:

Group A

Drugs in Phase I clinical trials and in Phase II trials in specified signal tumors. Protocol acceptance and drug distribution are limited to either members of a Phase I work group or cancer therapy evaluation program clinical contractors and grant supported cooperative groups.

Group B

Drugs that have gone beyond initial Phase II studies and have been deemed of clinical interest at the New Drug Liaison Meetings and by the Cancer Therapy Evaluation Therapy Program staff. Protocol acceptance and drug distribution are extended to include investigators submitting protocols through cancer centers participating in the New Drug Studies mechanism, cooperative groups, Cancer Therapy Evaluation Program contracts. As well, cooperative groups and Cancer Therapy Evaluation Program contractors.

Group C

Drugs that have demonstrated efficacy within the tumor type in more than one study which alters the pattern of care of the disease in question, and that safely administered by properly trained physicians without requiring specialized supportive care facilities.

Exhibit A is a copy of the "Drug Development and Assignment Report as of August 18, 1983. This lists the various drugs as to their grouping, be it A, B, or C. In this particular report, there are also subdivisions of Groups A and B. Group A1 refers to members of a Phase I working group. Group A2 refers to cancer therapy evaluation program clinical contractors and grant supported cooperative groups. Group B1 concerns investigators who are participating in the new drug studies mechanism, cooperative groups, cancer therapy evaluation program contractors. Group B2 is cooperative groups and cancer therapy evaluation program contractors. Group B3 are drugs available only for existing studies to the above-mentioned groups and Group B4

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identifies an existing investigational new drug whereby the IND will be closed. There are no subdivisions for Group C.

Exhibit B is the memorandum from the deputy assistant secretary for health research, statistics, and technology dated November 1, 1979. Exhibit B further discusses and summarizes the groupings of investigational drugs. The conclusion reached by the assistant secretary for health was "We compliment HCFA (Health Care Finance Administration) in its decision to reimburse for hospitalization and associated costs for Group C drugs. We believe that we should also provide reimbursement for Group A and Group B drugs."

Exhibit C is a memo from Blue Cross and Blue shield of Greater New York dated March 21, 1983. That memo states that providers are reminded that experimental drugs are statutory exclusions and should not be billed to the Medicare program. Reference is made to Section 210.3B of the Medicare Hospital Manual (HCFA publication #10).

The chairman of the Clinical Practice Committee of ASCO has received a number of letters from various physicians in different parts of the United States indicating that their patients have received retrospective rejections for hospital care associated with the use of investigational drugs. It appears that this problem may become more widespread. A more frequent turn of events would have an adverse effect upon clinical research relating to the cancer patient. These retrospective rejections not only are concerned with Medicare, but also Blue Cross which in a number of contracts specifically excludes coverage for "research purposes".

From the attached exhibits, it appears that there are differing viewpoints as to whether investigational drug related hospitalizations and medical care are reimbursible expenses. For example, Exhibit B supports such payments whereas Exhibit C precludes such payments.

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It is recommended that ASCO do the following:

1. Develop guidelines for the HCFA concerning reimbursement for care associated with the use of Group A, Group B, and Group C drugs.
2. Approach various commercial carriers such as Blue Cross regarding their reimbursement policies for Group A, Group B, and Group C drugs.
3. ASCO to develop a reasonable and constructive attitude for such a reimbursement policy.

ACKNOWLEDGEMENT

The author thanks the members of the Clinical Practice Committee for their comments and reviews of this position paper.

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Blue Cross
Blue Shield
of Greater New York

MEDICARE
PROVIDER BULLETIN

HOSPITAL

BULLETIN NO. 55

DATE March 21, 1983

SUBJECT: BILLING INFORMATION FOR CHEMOTHERAPY SERVICES

The following guidelines have been prepared to assist your staff in proper billing of chemotherapy services.

The administration of chemotherapy is normally considered an outpatient service, billed on the HCFA-1483 claim form.

Any services rendered a patient who remains in the hospital for less than 24 hours must be reported as outpatient services and billed on the HCFA-1483. These regulations can be found in Section 210. A of the Medicare Hospital Manual (HCFA Pub. 10), and were also addressed in our Hospital Bulletin No. 36, October 16, 1981.

It is recognized that in some instances there will be inpatient stays for chemotherapy treatments that are medically necessary and may require acute inpatient stays beyond the 24 hours. Inpatient claims submitted for short lengths of stay are subject to medical review, particularly if the diagnosis indicates the admission may have been for chemotherapy.

If the services are administered in less than 24 hours (the actual treatment) but the length of stay in the hospital is over 24 hours, the need for further acute inpatient care must be documented. Without documentation for further acute inpatient care the claim will be rejected, and will be subject to provider liability. This bulletin constitutes notice to providers that such services will not be covered and the waiver of liability provision will not apply.

EXPERIMENTAL DRUGS AND PROCEDURES - A REMINDER

During the past few months the Medicare Part A Center has received several claims for experimental drugs in conjunction with chemotherapy treatments. Providers are reminded that experimental drugs and any hospital stays for the purpose of administering experimental drugs are statutory exclusions and should not be billed to the Medicare Program. This is clearly detailed in Section 210.3 B of the Medicare Hospital Manual (HCFA Pub. 10).

If further information is needed, please contact your local Provider Relations Representative or call the Medicare Part A Center at 1-800-962-3628 or Provider Relations at (315) 474-4189.

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AMERICAN SOCIETY OF CLINICAL ONCOLOGY POSITION CONCERNING PARENTERAL CHEMOTHERAPEUTIC AGENTS

BY DAVID PRAGER, M.D.

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ASCO POSITION CONCERNING PARENTERAL CHEMOTHERAPEUTIC AGENTS

By David Prager, M.D.

INTRODUCTION

Over the past years, both members and nonmembers have written to the American Society of Clinical Oncology (ASCO) about reimbursement issues concerning chemotherapeutic drugs. As a result of numerous inquiries upon this subject, the chairman of the Clinical Practice Committee (CPC) developed a draft position which was subsequently reviewed by the CPC. The CPC of ASCO approved a final version that was then presented to the ASCO board of directors. On May 5, 1984, the ASCO board of directors approved that document for dissemination to the membership. The following is a review of that position paper concerning chemotherapy administration, chemotherapy reimbursement and the endorsements of ASCO.

CHEMOTHERAPY ADMINISTRATION

Regarding chemotherapeutic agents, there are two separate aspects: the administration of the drug and the payment for the drug. Concerning the administration of the drug, at the present time, there are limited number of procedure codes available through Part B of Medicare and most other health

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insurors for the administration of parenteral anti-neoplastic drugs[1](See table #1). The great majority of anti-neoplastic drugs would be administered as I.V. push (procedure code 96033) or I.V. infusion (procedure code 96035). However, there are more than two ways that chemotherapy can be administered. That is the reason why the common procedure terminology, version 4 (CPT-4) was promulgated during April, 1983[1] (See table #2). Usually a patient does not receive a single agent form of intravenous chemotherapy because most treatment programs revolve around the use of multiple drugs. The multi-agent treatment program may require all agents to be given by intravenous push or some of the agents to be given by intravenous drip, depending upon the dose, drug, and patient variables. The two existing procedure codes (96033 and 96035) really do not take into account the many contemporary developmental aspects that have occurred regarding the administration of multi-drug chemotherapy. Therefore, the CPT-4 terminology was developed in order to offer a more accurate definition for the commonly utilized techniques concerning the administration of anti-neoplastic drugs. The current CPT-4 as noted in Table 2 lists eighteen distinct procedure codes that are utilized for the parenteral administration of

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chemotherapy. CPT-4 has been approved by the CPT group of the American Medical Association for implementation by Medicare and other third party health insurors. Implementation is on a voluntary basis based upon due review by the appropriate third party insuror. Medicare through the Health Care Finance Administration (HCFA) plans to implement the use of CPT-4 terminology as of January, 1985.

CHEMOTHERAPY DRUG REIMBURSEMENT

Chemotherapy drug reimbursement is a much more complex issue due to the variable reimbursement policies of different health insurors. Generally, there are two broad types of health insurors - charge payors or cost payors. In the physician's office, the charge payor will usually pay "reasonable" charges for parenteral anti-neoplastic drugs. Examples of such charge payors are companies such as Aetna, Prudential, Provident, and Travelers, to mention a few of the commercial charge payors. Health insurors which are examples of the cost paying insurors are Blue Shield and Medicare. Blue Shield coverage for parenteral chemotherapeutic agents is quite variable depending upon the benefits available in the contract with the subscriber. Medicare is more standardized as to the benefits since reimbursment for parenteral drugs is a covered benefit under

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Part B of Medicare. The administrative arm of Medicare is the HCFA. HCFA uses as its guideline for drug reimbursement the "Drug Topics Red Book".[2]

The Drug Topics Red Book is a commercial guide to products and prices. This is published yearly with updates by the Medical Economics Company which is located in Oradell, New Jersey. The "Red Book" publishes what is known as the average wholesale price (AWP). The AWP is the "price paid by the retailer to the wholesaler and is either that suggested by the manufacturer or independently determined AWP which is proceeded by the symbol AWP. These AWP prices are independently obtained and calculated by the Red Book editorial staff from a representative group of wholesalers located in different areas of the country."[2] It is important to understand how the Drug Topics Red Book generates the AWP because the AWP is used by Medicare as the basis for determining patient or physician drug reimbursement. As well, drug price increases (rarely decreases) do occur frequently during the year. Those price changes are usually not reflected in the reimbursement by Blue Shield or Medicare.

Many pharmaceutical firms will not permit direct purchasing by a physician (see Table 3). Therefore, the physician may

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purchase a drug at the retail price which by definition may be greater than the AWP. A further important aspect is that only three commercially available anti-neoplastic drugs are made by more than one manufacturer (see Table 4). This aspect seems to restrict competitive drug pricing. As a result of the Medicare drug reimbursement policy which is limited to the AWP, and the fact that the physician's cost may be greater than the AWP, the patient is encouraged to go to the outpatient or inpatient hospital area in order to receive their drug therapy. This in turn would generate increased expenses for Medicare and Blue Cross as a result of the patient being sent to the more costly hospital environment to receive those same drugs that can be given in a physician's office.[4]

A further disincentive to the physician for the treatment of cancer patients who are receiving anti-neoplastic agents is that there is usually no facility charge permitted for the services rendered in a physician's office. That is, if a patient were to stay in a physician's office for one or more hours to receive an infusion form of therapy, there is no mechanism for the use of such facilities. This further encourages the referral of the patient to go to the hospital as an inpatient or outpatient to receive the same therapy

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which can be given in a less expensive, but equally safe manner in a physician's office. Along those lines, Pennsylvania Blue Shield and Blue Cross performed a pilot study in 1979 through 1980 documenting that outpatient cancer chemotherapy in a physician's office was at least one-third less expensive than the same services offered in the outpatient area of a hospital.[3] As a result of that study, Pennsylvania Blue Shield established payment for parenteral anti-neoplastic drugs as a standard statewide benefit in a physician's office.

There is ample justification for drug reimbursement to be an amount greater than the AWP. Cost reimbursement for parenteral chemotherapy drugs is not appropriate for a physician's office. The cost reimbursement approach does not apply since the private practitioner's office does not receive the same financial advantages that the cost reimbursed hospital enjoys. Such financial advantages for the non-for-profit hospital are no taxes and low interest governmental loans. There are appropriate reasons for parenteral drug reimbursement in the physician's office to be an amount greater than the invoice price. For example, the stocking of a wide variety of anti-neoplastic drugs

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involves additional expenses which are above and beyond the invoice prices (See Table 5).

SUMMARY STATEMENT

In summary, the American Society of Clinical Oncology endorses the following statements:

1. Implementation of the CPT-4 terminology concerning the administration of cancer chemotherapeutic drugs.

2. Reimbursement for parenteral anti-neoplastic drugs to be an amount greater than the cost to the physician so as to take into consideration matters such as drug losses due to short shelf life (nonrefundable), drug wastage (patient refusal, technical problems), drug pricing changes, bad debts, time spent on restocking drugs, and time spent on ordering drugs.

3. Where appropriate procedures justify such, a facility fee should be available for prolonged patient stay in a physician's office for cancer chemotherapeutic drug administration.

ACKNOWLEDGEMENT

The author thanks the members of the Clinical Practice Committee for their comments and reviews of this position paper.

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TABLES

TABLE 1. PROCEDURE CODES - CHEMOTHERAPY ADMINISTRATION

96032	- Administration of chemotherapy for malignant disease, subcutaneous or intramuscular
96033	- Administration of chemotherapy for malignant disease, intravenous or intra-arterial
96035	- Administration of chemotherapy for malignant disease, infusion
96040	- Administration of chemotherapy for malignant disease, perfusion

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TABLE 2. CURRENT PROCEDURAL TERMINOLOGY (CPT-4)

CHEMOTHERAPY INJECTIONS

Procedures 96500-96549 are independent of the patient's office visit. Either may occur independently from the other on any given day, or they may occur sequentially on the same day. Oncologists may see their patients at two to four week intervals with none to five chemotherapy procedures between visits.

96500 Chemotherapy injection, intravenous, single premixed agent, administered by qualified assistant under supervision of physician; by push technique.

96501 by infusion technique

96504 Chemotherapy injection, intravenous,multiple premixed agents, administered by qualified assistant under supervision of physician or by physician; by push technique.

96505 by infusion technique

96508 Chemotherapy injection, intravenous, complex, using one or more agents requiring mixing, administered by qualified assistant under supervision of physician or by physician; by push technique

96509 by infusion technique

96510 by infusion technique, prolonged, requiring attendance up to one hour

96511 by infusion technique, prolonged, each additional hour up to a total of eight (8) hours

96512 by infusion technique, prolonged, up to a total of several days, involving the use of portable pump.

(use 96512 in addition to code for intravenous catheterization; see 36000-36010, 36400-36425, 36480-36491)

96520 Portable pump refilling and maintenance

(Use 96520 in addition to 96512)

96524 Chemotherapy injection, complex, administered by physician, arterial infusion technique.

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TABLE 2., continued.

96526 Chemotherapy injection, complex, administered by physician, prolonged intra-arterial therapy infusion technique, up to several months

(Use 96526 in addition to code for intra-arterial catheterization; see 36100-36299, 36640-36660)

(For monitoring of an intra-arterial chemotherapy, drip or foced infusion, see 36620-36625)

(For implantation of infusion pump in hepatic artery system for liver chemotherapy, see 36260-36362)

96530 Implantable pump filling and maintenance

(Use 96530 in addition to 96526)

96535 Chemotherapy injection, complex, requiring thoracentesis and/or paracentesis, administered by physician, intracavitary

96538 Chemotherapy injection, requiring lumbar puncture, administered by physician

96540 Chemotherapy injection, intrathecal via reservoir, single or multiple agents, administered by physician

(For insertion of subarachnoid catheter for infusion of drug, see 63750)

96545 Provision of chemotherapy agent

(For radioactive isotope therapy, see 79000-79999)

96549 Unlisted chemotherapy procedure

Source: Physicians' Current Procedural Terminology. 4th Edition. Order Department OP-341. American Medical Association PO Box 10946 Chicago, Illinois 60610

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TABLE 3

DRUG MANUFACTURERS - PERMIT DIRECT PURCHASE

ADRIA LABS
BRISTOL LABS
LEDERLE LABS
MEAD JOHNSON
MERCK, SHARPE AND DOHME
ROCHE LABS
UPJOHN LABS

DRUG MANUFACTURERS - NO DIRECT PURCHASE

BURROUGHS WELLCOME
DOME LABORATORIES
ELI LILLY
STUART PHARMACEUTICALS

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TABLE 4

COMMERCIALLY AVAILABLE DRUGS

ADRIA LABS: ADRIA, 5FU, CYCLO, MTX

BRISTOL LABS: CCNU; BCNU; BLEO; MTX; C-DDP; O,P-DDD; MITO-C; VP-16

BURROUGHS WELLCOME: CLB, L-PAM, 6-MP

DOME: DTIC

LEDERLE: MTX; CF

LILLY: VCR; VLB

MEAD JOHNSON: CYCLO

MERCK, SHARPE & DOHME: AMD, L-ASP, HN2

ROCHE LABS: 5FU; PROC

STUART: TAM

UPJOHN: ARA-C

TABLE 1 - ABBREVIATIONS

ADRIA	- Doxorubicin	HN2	- Nitrogen mustard
AMD	- Actinomycin D	L-ASP	- Asparaginase
ARA-C	- Cytosine arabinoside	L-PAM	- Alkeran
BCNU	- Carmustine	MITO-C	- Mitomycin
BLEO	- Bleomycin	MTX	- Methotrexate
CCNU	- Lomustine	O,P-DDD	- Mitotane
C-DDP	- Platinum	PROC	- Procarbazine
CF	- Citrovorum factor	6-MP	- Mercaptopurine
CLB	- Chlorambucil	TAM	- Tamoxifen
CYCLO	- Cyclophosphamide	TG	- Thioguanine
DTIC	- Dacarbazine	VLB	- Velban
5FU	- Fluorouracil	VCR	- Vincristine
		VP-16	- Etoposide

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TABLE 5. PARENTERAL DRUG COSTS (DIRECT AND INDIRECT)

Time spent to order drugs

Time spent to restock drugs

Drug losses due to short shelf life (nonrefundable)

Drug wastage (patient refusal, technique)

Bad debts

Drug pricing changes

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2. Drug Topics Red Book. Annual Pharmacists' Reference. Medical Economics Company. Oradell, New Jersey.

3. Prager, David. Chemotherapy in the Physician's Office. Pennsylvania Medicine 87: 50-52, 1984.

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[From the Chronicle, May 1, 1985]

Doctors Open Office Here for Low-cost Cancer Screening

(By Bess Keller)

A group of area radiologists have spent $400,000 to open a north Bethesda office that features low-cost x-rays to screen for breast cancer.

"With increased volume, we are able to lower the cost," said Dr. Peter Dunner, who started a similar breast cancer screening program at the group's office in Fairfax, Va. The charge for a breast x-ray, known as a mammogram, is $50.

The new x-ray and ultrasound center will be able to do up to 20 breast screenings a day, according to Dunner. Opened by Washington Ultrasound Associates last month, the office is located in the Camalier Building at 10215 Fernwood Road.

Washington Ultrasound's Fairfax office, open about a year, is already booked for screenings through June, Dunner said, adding that he expects the Bethesda office to be equally busy soon.

The American Cancer Society recommends mammograms every one or two years for women aged 40–49, and every year for women 50 and over. Early detection of breast cancer vastly increases a woman's chance of survival, medical experts say, and mammograms detect some breast changes before they can be felt.

To be eligible for the low-cost screening, women must have no breast complaints or symptoms. Most are referred by their doctors, but a woman may come on her own if she names a doctor to receive the radiologist's report. Dunner said.

The x-ray session, in which a low-dose mammography machine takes four pictures of the breasts requires about 15 minutes. The mammogram is then interpreted by a radiologist, who sends a written report to the woman's doctor within 24 hours, Dunner said.

If the radiologist finds any abnormality, the patient's doctor is contacted by phone.

"I've seen a tremendous and dramatic rise in the number of women seeking mammograms" in the past four or five years, said Dunner. The radiologist said the change was largely due to the American Cancer Society's recommendations on breast cancer, which were revised two years ago.

While the Society has recommended for years that older women be x-rayed, in 1983 it said mammograms every one or two years should begin at age 40. The new recommendation was the result of studies showing that one-third of breast cancers appear in women aged 35 to 49 said Joann Shellenbach, a spokeswoman for the American Cancer Society headquarters in New York.

The recommendation also took into account improvements in x-ray machines, which had significantly reduced the radiation dose per x-ray, making the mammograms themselves safer Shellenbach said. The benefits she said, now far outweigh the risks.

The society also advises that women between the ages of 35 and 40 go for a "baseline" mammogram. Because every woman's breasts are different, an x-ray that pictures healthy breasts can help doctors detect later unhealthy changes, according to the spokeswoman.

But, said Shellenbach, because of the cost of the x-rays and lingering fears of radiation, it has not been easy to convince women to routinely get the mammograms. Insurance companies do not reimburse women for the cost, which in most places averages about $100 per series, she said.

In addition to the breast screening program, Washington Ultrasound's Bethesda office offers breast consultations, including breast ultrasound; pelvic ultrasound for pregnant and non-pregnant women; and chest x-rays.

[From the Oncology Times, August 1985]

A new breast cancer screening program is being offered by the department of radiology at the Medical Center of the University of California, San Francisco. The program offers lost-cost ($30) mammograms to women from a mobile van that travels to shopping or downtown areas and remains for a week at a time. Since the screening program began, 450 patients had mammograms in the mobile van. Of these, five were found to have otherwise unsuspected breast cancer, and four of

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these tumors were not detectable by palpation, even with the aid of x-rays to locate them. Women need the approval of their physicians to have the mammograms. The program is not for women with known lumps, cysts, or complex breast abnormalities, stressed Edward Sickles, MD, the program's director. The van is staffed by x-ray technologists, who return the x-rays at the end of the day to UCSF, where they are developed and analyzed. Results are mailed the following day to the woman's physician.

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APPENDIX 3

NEWSPAPER AND MAGAZINE ARTICLES CONCERNING DES, ALONG WITH A COPY OF S. 551, SENATOR RIEGLE'S BILL ON DES VICTIMS. SUBMITTED BY ROSE KUSHNER

[From the Washington Post, Dec. 13, 1977]

ANTI-MISCARRIAGE DRUG DES ADDS TO MOTHER'S CANCER RISK

(By Morton Mintz)

New evidence indicates that a drug prescribed in hopes of averting miscarriages in an estimated 2 million women sharply increased their risk of developing often fatal cancer.

The new findings come 6½ years after the discovery that sometimes-fatal vaginal and cervical cancer occurred in about 200 daughters of women who had taken the drug, DES, as long as a quarter-century earlier.

In a further report two years ago, scientists said that low sperm counts and other birth defects in the reproductive tract were showing up in thousands of sons of DES mothers.

In the new data, one key finding is that breast-cancer rate 76 percent higher among women who had taken large doses of the hormone in 1950–1952 than among controls—otherwise similar women who had taken a dummy drug.

Specifically, 31 of 693 DES mothers developed breast cancer, compared with 17 among 663 controls. The breast cancer death rate was three times higher among the DES mothers: 12 vs. 4.

In addition, 16 DES mothers developed other so-called endocrine-related cancers—of the cervix, lining of the uterus, ovaries and colon, compared with 10 controls. In the DES women, six of the cases were fatal; in the controls, two.

Dr. John C. Bailar, editor of the Journal of the National Cancer Institute, told a reporter that the cancers occurring in DES mothers appear to be "killers," meaning that the frequency with which they are fatal, rather than being treatable with mastectomies, is high.

Dr. Sidney M. Wolfe, director of the Health Research Group, which is financed by Ralph Nader's Public Citizen, Inc., disclosed the evidence—which he termed "preliminary"—yesterday in a letter to Joseph A. Califano Jr., Secretary of Health, Education and Welfare.

He urged Califano to arrange an alert of all DES mothers to the need for periodic examinations, and to direct the National Institutes of Health to coordinate follow-ups at all medical centers that dispensed DES, with the bills to be paid by drug companies that "profited from DES sales."

Wolfe also requested Califano to ask all physicians to search their files for women to whom they gave DES. Some prescribed it as a "precaution" whenever a woman patient became pregnant, even if there was no sign of an impending miscarriage.

In addition, Wolfe asked the secretary to try to expedite the slow-moving effort of the Food and Drug Administration to bar DES from cattle feed, where it is used as a growth stimulant, and to try to limit use of DES as a "morning after" contraceptive pill to cases of rape and incest.

After reviewing the new DES data, Dr. Bailar said, "It does look like a very bad situation, and it's likely to stay that way."

He termed the evidence of cause and effect "very suggestive" but "not conclusive." Conceivably someone will come up with an explanation other than DES, but, Bailar said, "I don't know what it would be."

Wolfe derived the evidence from an interim report by University of Chicago scientists on a follow-up of women who were given DES in a carefully controlled experiment at the University Chicago Lying-In Hospital over a 20-month period which ended in November, 1952.

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The scientists dated the report Aug. 31 but didn't file it—with the National Institute of Child Health and Human Development, which is financing the study—until Oct. 28. Four contract consultants are to meet late next month to discuss the report.

At Wolfe's request, the Public Citizen Litigation Group got a copy of the report under the Freedom of Information Act for him to analyze. He urged Califano to try to speed government handling of such reports hereafter.

The results of the 1950s experiment undermined claims that the hormone prevented miscarriages. To this day, the FDA says, there is no substantial evidence of effectiveness in this usage.

Physicians continued heavy prescribing of DES as late as 1971, almost 20 years after evidence of ineffectiveness had been published. In 1974, the number of prescriptions fell to a low of 11,000. Since then, the number of prescriptions written for DES to avert spontaneous abortions has been negligible.

The university scientists began to look at the incidence of cancer in DES mothers in the experiment after a nurse participating in the followup of their children mentioned that she thought many of the women had died of breast cancer.

DES is an estrogen. The cancer causing potential of estrogens has been known for decades. Two years ago, scientist reported that the approximately 5 million women talking estrogens over a long period to ease postmenopausal symptoms had a rate of cancer of the lining of the uterus at least five times normal.

Six months later, Dr. Robert N. Hoover, head of the Cancer Institute's Environmental Studies Section, co-authored a report suggesting that sustained use of postmenopausal estrogens also could cause breast cancer. Yesterday, he said in a phone interview that the new DES data "look worrisome to me."

The Institute's Bailar described prescribing of estrogens for sustained use by postmenopausal women as "a stupid, stupid thing to do. I think it's just insane."

He was asked if there is possible relevance of the new DES findings to oral contraceptives, most of which combine an estrogen with another hormone called a progestogen. Currently, an estimated 10 million American women take them.

"I would be almost as strong about the oral contraceptives," Bailar said "No woman who takes those really understands what they may do to her in the future, and the same goes for doctors who prescribe them."

The university scientists, in a preliminary check on DES mothers, found that of 430, nine had reported breast cancer and six had died. Among 320 controls there was one case, and it was fatal. In a proposal for federal financing of a study of the women, the scientists termed the finding "alarming" and follow-ups of "paramount importance."

The much larger group studied as of Aug. 31—693 DES mothers, 668 controls—is about 83 per cent of the total involved in the 1950s experiment.

In the letter to Califano, Wolfe wrote that, in addition to excess cases of breast cancer, two other findings implicate DES: the higher speed at which the disease developed in DES mothers as opposed to controls, and the larger proportion of under 50 victims who had taken DES.

As to speed, by January, 1963, for example, four DES mothers but none of the controls had developed breast cancer.

The average age of DES women and controls during the 1950–52 experiment was nearly the same: 27.8 vs. 27.6.

Subsequently, 30 women developed breast cancer before age 50. Twenty three were DES mothers. But of 18 over-50 women who developed the disease, 10 were controls.

The cases in under-50 DES women represent a "very substantial excess that leaves him much concerned," Bailar said in a phone interview. Noting that many of the DES mothers are not yet 50, he said it is possible that an abnormal rate of breast cancer in over-50 DES users may yet show up.

In April, Assistant Secretary of State Patsy T. Mink and two other women filed a $77 million class action suit against the University and Eli Lilly & Co., a leading DES supplier.

They charged that the university administered DES to the women without their knowledge, telling some of them they were getting vitamin pills.

Many of the women bore sons with birth defects of the reproductive tract. None is known to have borne a daughter with vaginal or cervical cancer.

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[From the Washington Star, Dec. 13, 1977]

Breast Cancer Risk Boosted by DES, Nader Unit Says

(By Robert Pear)

Nearly seven years ago doctors at Massachusetts General Hospital concluded that a synthetic hormone given to pregnant women, in the belief that it would prevent miscarriage, had increased the chances of vaginal cancer in the women's daughters.

Now Ralph Nader's Health Research Group says there is another hazard—a substantially increased risk of breast cancer—among women who actually took the hormone, known as diethylstilbestrol, or DES.

Dr. Sidney M. Wolfe, director of the Health Research Group, estimated yesterday that 2 million women had taken DES over the last several decades although he said, there is no evidence that it is effective in preventing miscarriages.

In a letter to Joseph A. Califano, Jr., secretary of health, education and welfare, Wolfe urged the government to take steps to notify DES mothers that they may have an increased risk of developing breast cancer.

He also asked the government to outlaw use of DES as a "morningafter" contraceptive pill and as an additive to the food supply.

A spokesman for the Food and Drug Administration said that the drug, a synthetic estrogen, is not approved for use as a "morning-after" pill and that FDA is in the midst of an administrative proceeding to ban its use as a growth stimulant in cattle.

John C. Bailar III, editor of the Journal of the National Cancer Institute, who has examined the data cited by Wolfe, said: "I believe this finding with respect to the mothers is entirely new. At least I was not aware of it."

He said the data appeared "profoundly disturbing." But at this point, he said, there is no proof of a cause-and-effect relationship between administration of DES and an increase in breast cancer.

Bailar was one of the first scientists to suggest that x-rays used in the nationwide breast cancer screening program might produce the very type of cancer they were designed to detect. A thorough re-evaluation of the program and major changes followed.

Wolfe's warnings about DES were based on data gathered by researchers at the University of Chicago including Dr. Arthur L. Herbst.

Working at Massachusetts General Hospital in 1971, Herbst and others were the first to link DES taken during pregnancy with a rare form of vaginal cancer in female offspring.

Their studies are considered a classic of medical detective work. But Herbst now does not go along with Wolfe's conclusion.

In a telephone interview yesterday, Herbst said, "Our data do not demonstrate an increased risk of breast cancer among mothers who received DES during pregnancy."

Herbst said he and his colleagues at Chicago are investigating whether there may be a correlation such as Wolfe described.

"Is there concern? Yes," said Herbst, chairman of obstetrics and gynecology at the University of Chicago Medical School. "But there's no evidence of an increase at least so far. I don't know what's going to happen 20 years from now."

DES, a man-made version of a natural female sex hormone, has triggered a number of lawsuits.

Last April, for example, Assistant Secretary of State Patsy T. Mink and two other women filed suit against the University of Chicago and a leading drug company, stating that during pregnancy they had been given DES without their knowledge. They asked $77 million in damages for themselves and hundreds of other women who had received the drug in an experiment at the Chicago Lying-In Hospital.

In the past two years, doctors have reported that male as well as female offspring of DES mothers may suffer adverse effects. For sons of women who took DES during pregnancy, the risk is abnormalities of the reproductive system including sterility.

Compounds containing natural and synthetic versions of the feminine sex hormones known as estrogens are used both to prevent conception and to relieve menopausal symptoms.

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Cancer Risk Among Women Exposed to Exogenous Estrogens During Pregnancy[1,2]

O. C. Hadjimichael, *M.P.H.*,[3,4] J. W. Meigs, *M.D.*,[3] F. W. Falcier, *M.A.*,[5] W. D. Thompson, *Ph.D.*,[3] and J. T. Flannery, *B.A.*[6,7]

ABSTRACT—A cohort of 3,139 obstetric patients, who delivered children between 1948 and 1965, was followed retrospectively to assess the relationship between exposure to diethylstilbestrol [(DES) CAS: 56-53-1; α,α'-diethyl-4,4'-stilbenediol] or other estrogenic substances during pregnancy and subsequent cancer incidence. Among the 1,531 women exposed to DES, the relative risk (RR) for all cancers was 1.46 [95% confidence interval (CI), 1.07-2.00]. The RR for cancers of the breast, cervix, and ovary were 1.37 (adjusted), 1.40, and 2.83, respectively, but none of these estimates was statistically significant. For breast cancer an RR in excess of 2.28 can be excluded, with 95% CI for doses averaging 2,100 mg. Within the exposed group there was no evidence for a dose-response relationship.—JNCI 1984; 73: 831-834.

Because estrogens have been associated with the induction of cancer (*1-3*), the hypothesis has been put forward that mothers who were given DES or other exogenous estrogens during pregnancy to prevent spontaneous abortion may be at risk of subsequent development of cancer. This study examines the experience of a group of women who were exposed during pregnancy to estrogenic substances, and most commonly to DES, to assess whether they have an elevated risk for cancers of the breast and the reproductive tract.

The dose received by the mother may be an important determinant of subsequent effects. No excess breast cancers were found in two studies (*4, 5*), one of which (*4*) evaluated estrogen exposures that averaged 11-12 g. A third study (*6*) showed a statistically significant excess of breast cancer and benign uterine tumors in women who took large doses of estrogenic substances (the estimated mean dose of DES was 16.5 g and of ethisterone 13.8 g).

This report presents the results of a cohort study that involved a lengthy follow-up and relatively low doses of DES or other estrogens.

METHODS

A cohort of 5,315 mothers was identified in 11 offices of obstetricians and gynecologists in Fairfield and New Haven counties, Connecticut, with the cooperation of the Connecticut Chapter of the American College of Obstetrics and Gynecology, for the purpose of conducting a retrospective study of the health effects of estrogens, particularly DES (CAS: 56-53-1; α,α'-diethyl-4,4'-stilbenediol), that was administered during pregnancy. The 11 offices were selected on the basis of geographic availability, numbers of records held from 1945 forward, and completeness of record keeping (indicated by preliminary visits of research staff). DES was prescribed during pregnancy for 1,706 of these mothers from 1946 to 1965. A variety of other exogenous estrogens was administered to 204 women.

A comparison group of 1,405 women was selected from the same physicians' records and was matched to the exposed women by age within 5 years, race, sex of offspring, and date of the index pregnancy within 6 months. A woman was eligible for the nonexposed group if her physician's record contained no evidence that any estrogenic substance had been prescribed during any pregnancy. Information was not available on possible exposure to estrogens among those nonexposed women who changed physicians subsequent to the index pregnancy. The principal reason that estrogens were prescribed by physicians for the women in the cohort was to reduce the risk of abortion. Because the nonexposed women experienced low rates of abortion (9.6%, some of which may have not been spontaneous), very few of these women would be expected to receive estrogens during later pregnancies.

Choice of exposed and nonexposed subjects within the same physician's office controlled for socioeconomic status to some extent, because office locations and scale of fees generally attract patients of similar socioeconomic status.

Information abstracted from the physicians' records included demographic data, pregnancy history, and

Abbreviations used: CI=confidence interval(s); CTR=Connecticut Tumor Registry; DES=diethylstilbestrol; PY=person-years; RR=relative risk(s); SIR=standardized incidence ratio.

[1] Received January 26, 1984; accepted May 31, 1984.

[2] Supported by Public Health Service (PHS) grant CA-20347 from the Division of Extramural Activities, National Cancer Institute (NCI); by PHS grant N01CP-61002 from the Division of Cancer Cause and Prevention, NCI; by grant PDT144 from the American Cancer Society; and by the Institute of Occupational Medicine and Hygiene, Yale University School of Medicine.

[3] Connecticut Cancer Epidemiology Unit and Department of Epidemiology and Public Health, Yale University School of Medicine, New Haven, Conn. 06510.

[4] *Address reprint request to* Olympia Hadjimichael, Department of Epidemiology and Public Health, Yale University School of Medicine, 60 College St., New Haven, Conn. 06510.

[5] Merrill Lynch Inc., 195 Church St., New Haven, Conn., 06510.

[6] Connecticut Tumor Registry, Hartford, Conn. 06106.

[7] We thank Dalia Laub, Susan Frörer, William Mangine, and Gregory Morgan for their valuable help with the data collection and management.

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99TH CONGRESS
1ST SESSION

S. 551

To provide for the establishment of a registry to identify and aid individuals who have been exposed to the drug diethylstilbestrol (DES), and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28 (legislative day) FEBRUARY 18, 1985

Mr. RIEGLE introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To provide for the establishment of a registry to identify and aid individuals who have been exposed to the drug diethylstilbestrol (DES), and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) the Secretary of Health and Human Services (hereafter in this Act referred to as the "Secretary") shall establish a national registry to facilitate—

(1) the identification of women who took diethylstilbestrol while pregnant;

(2) the identification of the children of such women who were exposed to diethylstilbestrol in utero;

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(3) informing the women and children described in paragraphs (1) and (2) of new developments related to diethylstilbestrol;

(4) the dissemination of public education regarding the health effects associated with diethylstilbestrol and the importance of medical care to detect and treat such effects;

(5) the dissemination of information to health professions personnel on the necessity of identifying individuals exposed to diethylstilbestrol, the health effects associated with diethylstilbestrol, and the provision of medical care for the detection and treatment of such health effects; and

(6) the dissemination of information available in the registry to States who elect to establish programs described in section 2.

(b) In establishing the national registry under paragraph (1), the Secretary shall insure that no individual will be listed in the registry without the consent of the individual or, in the case of a minor, without the consent of the parent or guardian of such minor.

SEC. 2. (a) (1) The Secretary shall make grants to States to assist States in establishing programs to provide screening and diagnostic services for individuals exposed to diethylstilbestrol.

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(2) Any State receiving a grant to operate programs under paragraph (1) may operate such programs directly or make grants to public or private organizations within such State to operate such programs.

(b) No grant may be made under subsection (a) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall—

(1) contain such information and be submitted in such form and manner as the Secretary shall prescribe; and

(2) demonstrate to the Secretary's satisfaction that in each year of participation in the grant program the applicant will obtain the following percentages of its projected budget from non-Federal sources of funding:

(A) At least 25 percent in the first and second years.

(B) At least 50 percent in the third year.

(C) At least 65 percent in the fourth and fifth years.

(c) No State shall be eligible for more than five years of funding under this section.

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(d) For each fiscal year beginning after September 30, 1985, there are authorized to be appropriated $6,000,000 to carry out this section. Amounts appropriated under this section shall remain available until expended.

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APPENDIX 4

ADDITIONAL MATERIAL RECEIVED FOR THE HEARING RECORD

PREPARED STATEMENT OF ELAINE V. BEILIN, PH.D.

I wish I could be with you this morning, but today I am receiving chemotherapy as an outpatient at the Beth Israel Hospital in Boston. I tell you this not to make you feel sorry for me, but to remind you that this disease allows us few holidays; we must combat it swiftly and uncompromisingly.

Let me tell you briefly what I'm doing right now as a way of introducing you to my main purpose in writing this testimony: to convince you that the early detection and treatment of breast cancer is crucial not only to arresting the disease, but also to easing the trauma that the patient and her family will experience.

In the last six months, I have received my chemotherapy at an outpatient clinic at the Beth Israel Hospital. I go there two mornings a month to have blood tests and to receive the drugs intravenously. There, I find a strong support system of nurses, social workers, and doctors, who gather as a team. Under the direction of the brilliant and compassionate Dr. Lowell Schnipper, these professionals treat the whole person, physically and psychologically. There, I am encouraged to discuss the physical effects of these drugs and the mental stress that I, my husband, and two small children must face. Even though I am married to a physician and have received excellent care, we have felt the fear, and we have had to wonder about our future as a family.

But my strong feeling now, after a lumpectomy, radiation therapy, and chemotherapy, is that life has reclaimed us. Since the discovery of my cancer, I have not spent one night in the hospital; all my treatment, from surgery through to chemotherapy has been as an outpatient. I cannot emphasize enough how important this has been to my well-being and that of my family. With early detection, this is a possibility for treatment that removes much of the fear, allows the patient to function almost normally, and of course, keeps the costs down. It has also allowed me to continue my research and to work full-time as a college English teacher.

The history of my cancer is briefly this. Last January, doing a breast self-examination, I discovered a small mass in my right breast. After worrying about it for a week, I went to my gynecologist, who sent me immediately to a surgeon. The surgeon, Dr. Clinton Koufman, was not concerned about the mass at first, but did send me for a mammogram. Although this proved to be negative (I believe this had something to do with the angle of the mass), after the next month's examination, Dr. Koufman decided that the mass had changed, and that a lumpectomy and biopsy were in order. This was the most frightening moment of my life. I came through it because of my husband's support and because of the extraordinary counsel and comfort I received from Dr. Koufman. While a Massachusetts law ensures that physicians must give their patients all the alternatives of breast cancer treatment, one of the obstacles the breast cancer patient must deal with today is a bewildering array of possibilities—modified radical mastectomy, simple mastectomy, lumpectomy, radiation, chemotherapy—the more she reads, the more she discovers how physicians disagree; and where does that leave the patient? I was confused and I became angry when I realized that this country lags far behind European countries in research into alternatives to mastectomy. In England, I found that breast cancer patients have been routinely and successfully treated with lumpectomy and radiation for years.

What I learned at this stage was the crucial importance of finding the right physicians for me and then trusting their advice.

I began radiation therapy about a month after my lumpectomy. This involved daily trips to the hospital for six weeks; the treatment itself took about half an hour. This sounds onerous, but it was actually a revelation to me about the process of healing when you work with doctors, nurses, and technologists who treat you as a whole human being. Under the direction of Dr. Jay Harris, the radiation therapy department became for me not only the place where I was actively combatting my

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disease, but also a refuge from an outside world that, however innocently, labelled me as "the woman with cancer." Dr. Harris and his team were professional, but also personal: they talked willingly, they allayed my fears with explanations, with encouragement; they even gave me a place to sit that had bright windows, green plants growing, and an open space where I could see doctors and nurses coming and going, working together to treat their patients. Everything there said to me, "Life goes on."

And it does. Recently, I remarked to the oncologist, Dr. Schnipper, that it was ironic that a healthy person like me should get cancer. He replied, "You are a healthy person. You have a problem which we are treating, but you still remain a healthy person." Another time, he said, "Think, when you are finished with these treatments, you'll soar like a bird." What can I add to that, except the wish that all cancer patients might receive such care.

It is a very hard thing for a woman to take that first step, to take responsibility for herself by doing a monthly breast exam: we are so used to taking responsibility and caring for others that we often forget to put ourselves into the schedule. Then, when you find a lump, it doesn't get any easier. The very thought of cancer, of maybe losing a breast, can paralyze you with fear.

My message is simply this: with early detection, with treatment centers like the one I've found, there is life, there is hope.

STUDIO CITY, CA, *November 6, 1985.*

Congressman CLAUDE PEPPER,
Subcommittee on Health,
Washington, DC.

DEAR CONGRESSMAN PEPPER: As you must by now well know, breast cancer health care delivery is a problem with traumatic and sometimes fatal consequences. My knowledge of this problem comes from personal experience. In November of 1982 I went to the student health clinic at a major research university with the presenting symptom of a lump in my breast. I was told by an examining surgeon that the lump was cystitis, despite my protests about the abnormality of the lump. I was not given a mammogram due to a change in university policy. I received inadquate information about additional symptoms to look for. Perhaps most disturbing in retrospect, the surgeon told me that a well-informed patient would not have even brought a lump like mine to a doctor's attention. No follow-up appointments were scheduled. However the lump was reexamined again as part of a routine physical and no further diagnositic procedures were performed.

By the time the lump had reached 4 centimeters in size I was alarmed and returned for consultation, still assuming my condition was cystitis. The examining doctor was concerned and referred me to a surgeon who was not available for three weeks. No mammogram was scheduled. The nurse practitioner, under my questioning, did, however, express reservations about the university's mammogram policy and urged me to get one. At that point I consulted other physicians. Within a few days they had performed a mammogram and needle biopsy and diagnoised cancer. The radiologist said the cancer was clearly visible on the mammogram. Because of the length of time before my cancer was properly diagnosed, however, lumpectomy was not an option and I had involvement in five lymph nodes. My survival chances had been reduced from 90 to 40%.

I have sued the university. At this point six physicians, including two retained by the university's insurance company, have agreed that my health care was inadequate. The university's internal review board supported their management of my case. As far as I know, no changes have been made in their policy.

Other women in my professional and social networks have experienced similar problems with breast cancer diagnosis. Please realize these are well educated and economically advantaged women. Their health care was delivered by a variety of providers who should have met community medical standards. The women are at least as well informed as can be expected of a medical patient who is not a doctor or nurse. I am disturbed about how inadequate their care was, how insufficiently they were prepared to cope with medical resistance to their presenting symptoms and how often they were made to feel responsible for the failures in their medical care.

As a sociologist I am familiar with victim-blaming attributions. One important source of these in the case of breast cancer is, regrettably, patient education literature. The American Cancer Society literature on early detection of breast cancer through self-examination is intended to scare women into discovering and reporting lumps. However, it does nothing to inform women about what they should expect and demand from physicians or how to deal with physician resistance. The implicit

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message in the literature is that breast cancer can be diagnosed by feel when, in fact, this is unreliable even for physicians; and that misdiagnosis is the fault of the patient, not the doctor. This message is particularly galling to someone in my situation who received it at a point when it would do no good and in fact created illogical guilt, and anxiety about survival which is, alas, all too real.

For their part, doctors support the effort to inform patients and hold them responsible for self-monitoring, then discount patients' concern and symptoms. Patients tend to be diagnosed by statistical probability—age and family history—rather than careful attention to the patient's complaint and monitoring of changes in the patient's breasts. Patients who are misdiagnosed are treated as statistical abnormalities who failed to conform to their population profiles. Failures in health delivery and basic caring are ignored.

I understand you are drafting legislation providing insurance coverage for mammography with breast examinations. I applaud your effort. Based on my experience, I favor less physician discretion in the administration of mammograms. I don't think the only factor in their limited application is expense, however. Most patients—through no fault of their own—do not realize how important mammograms are, and doctors aren't giving them when they are warranted. In this regard I do think the American Cancer Society is making a real effort to establish higher standards of care through recommendations of mammograms for women at younger ages as a precautionary measure.

Another worthwhile public policy effort would be redirection of patient education to better inform patients about risk factors in breast cancer development, health care delivery obstacles, and diagnostic procedures and their implications. I also would like to see educational literature which covers a broader range of patient dilemmas at various stages of treatment and in different medical conditions. The little currently available is not properly distributed resulting in too little too late. Patients should be urged to be informed and persistent without assuming a burden of medical expertise.

Public policy also should address the need for physician education, not only of medical students, but doctors in practice. I think some of them lack basic knowledge about symptoms, cancer prevalence and diagnosic procedures. Better quality care is probably concentrated at those places where cancer cases converge well after the point at which early detection was possible. Hence, those doctors in a better position to make early diagnoses see relatively fewer patients and, without professional education, learn how to diagnose only at the expense of the cancer patient, if at all. Doctors also are weak in interactive skills which elicit critical patient contributions to diagnosis, and they discount the patient's own knowledge of her body.

Finally, I would hope that funds would be available for social science research documenting the extent of misdiagnosis of breast cancer and factors involved, as well as the effects of various sources of external medical review on the state of health care delivery for breast cancer patients.

I appreciate your concern with this issue and hope my experience can save at least one other person from the trauma I have suffered. I am going to be living with someone's medical mistake for the rest of my life—live, if I beat the odds.

Thank you for caring,

VICTORIA BILLINGS.

AMC CANCER RESEARCH CENTER,
OFFICE OF THE PRESIDENT,
Lakewood, CO, October 21, 1985.

Congressman CLAUDE PEPPER,
Chairman, Subcommittee on Health and Long Term Care, House Select Committee on Aging, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN PEPPER: I am Dr. Marvin A. Rich, President and Director of the AMC Cancer Research Center in Denver, Colorado. I am grateful for the opportunity to present testimony on behalf of House Bill 1402. In this testimony I present the views of the International Association for Breast Cancer Research representing 1200 physician and scientist members from 46 countries around the world, for which organization I serve as Secretary-General; for HIGH PRIORITY, the breast cancer research and information network which has a national breast cancer control program and membership across the country committed to the control of breast cancer through early detection and research, for which I serve as a member of its Board; the Association of American Cancer Institutes representing more than 70 member cancer centers across the country for which I serve as a member of the Program

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and Policy Committee. I am also a member of the Governor's Commission on Breast Cancer in Colorado and I have been engaged in cancer research and cancer control for twenty-eight years.

Breast cancer is a leading cause of cancer death in women, second only to lung cancer. In the United States alone, this year there will be 120,000 new cases of breast cancer and 39,000 deaths. It has been well proven that through early detection, many of those deaths could be prevented. If breast cancer is detected early, when still localized in the breast, 96% will be disease-free 5 years after diagnosis compared with 70% if the cancer has spread; 75% with localized disease will survive 10 years after diagnosis compared with 43% who have tumor spread to the lymph nodes and who benefit from chemotherapy. It should be noted that these figures may be understated as a consequence of the statistical methods employed. Early detection means in addition that women who experience breast cancer can enjoy a better quality of life, and be eligible for breast-conserving surgery offering them an enhanced cosmetic outcome for their disease.

Numerous studies have documented that mammography is an accurate method for the early detection of tumors. It is capable of detecting tumors too small to be palpated by either the patient or by her physician. In northern Europe large scale mammographic screening is routinely practiced as part of the health care delivery system and has demonstrated a very significant degree of effectiveness.

Why then have less than 5–10% of the American women eligible for mammographic examination had even one mammogram? Why are less than 50% of physicians in the United States ordering screening mammograms for their asymptomatic patients? The attitude of the public, their physicians and the segment of society that pays for medical care toward mammography, reflects a lack of understanding of its effectiveness, its safety, and its potential for very significant cost saving.

It is important to note that with today's modern equipment, one million mammograms could theoretically cause 1 cancer, but those same million mammograms could detect 800 breast cancers in asymptomatic women, potentially saving 800 lives.

In addition to lack of awareness, a major obstacle to the widespread use of mammography is cost. There is little understanding of the difference between screening mammograms with regularity of scheduling, greater volume, the need for fewer x-ray images, and the opportunity to read the films at more convenient times, and that of diagnostic mammograms which have far more stringent and costly requirements. Yet many medical facilities charge the same fee for these quite different procedures. Absolutely critical to the phenomenon by which the life saving technology of mammographic screening has become an elitist one, requiring either discretionary funds or sometimes impossible family sacrifice, has been the fact that many of the nation's largest third party payers of health care, including Medicare, will pay for diagnostic but not screening mammograms.

Early this year in Denver, we found that screening mammograms ranged in price from $95–$185. To determine if the factors described above could be modified, the AMC Cancer Research Center organized a region-wide low-cost mammographic screening program. This program called LIFESCREEN was carried out with the local CBS affiliate, KMGH-TV, a McGraw-Hill station, as the co-sponsor, with the support of HIGH PRIORITY and with the collaboration of 8 radiology centers in our region. The program, with major TV and press promotion invited women without symptoms to have screening mammograms at a cost of $60, essentially half price.

Colorado's First Lady Dottie Lamm served as Honorary Chairwoman of the project. Jeannie Fuller, a prominent Denver community leader, served as Chairwoman of the Women's Committee for Breast Cancer Control which helped to network the information about the program and its importance throughout the community. Denver was saturated with information describing the benefits of early detection. KMGH-TV prepared 30 Public Service Announcements and news spots and the Denver Post and radio station KNUS participated in the promotion. The kick-off included 2 HIGH PRIORITY seminars at the KMGH-TV studios which provided breast cancer information and stressed the importance of early detection and mammographic screening in an up-beat atmosphere which previously was shown to be highly motivational. For 3 days phone banks were set up to receive calls for registration packets. LIFESCREEN resulted in over 4,000 calls, far exceeding our projected target of 2500. The mammographic portion of the program is ongoing, and to date over 2000 women have taken LIFESCREEN mammograms which have revealed 200 significant medical problems including breast cancers and other pathological conditions.

The goals of the program were two-fold: motivational, for the consciousness of Denver's women to participate in mammographic screening on a regular basis as

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they do with Pap smears; and to inform and convince the radiologic community that by distinguishing between diagnostic and screening mammography, and by reducing the price of the latter, it would create a larger market that would make low priced screening an economic reality. It is of interest to note that some radiologists in our area have already lowered the cost of mammograms for asymptomatic women to $60.00 to $70.00.

In the spirit of H.R. 1402, those who are responsible for the cost of health care and for making the critical decisions for implementing health care programs must be made aware that in addition to the very significant humane aspects of disease prevention, there is an enormous economic benefit as well. It is useful to consider breast cancer as a model and to examine some cost estimates developed by Dr. E. Frei.

The estimated medical costs for a breast cancer patient who is cured of her disease because of early detection, ranges from $8,000 for adjuvant (preventive) chemotherapy plus an additional $12,000 for surgery and radiotherapy for a total of approximately $20,000. In contrast for the patient whose breast cancer is not detected early and consequently will likely die of her disease, the medical costs are $60,000. If these costs are multiplied by the number of women (both pre- and postmenopausal) who will develop breast cancer this year the cost saving of early detection for all of these women would be $204 million. It is also useful to calculate the additional costs that accrue to the individual, to the family and to society as the result of the loss of a key income generating and tax paying family member. Using the conventional economic technique of measuring the earning and imputed value of household services during the years gained by their survival and correcting for the fact that future earnings must be discounted, because future earnings are not as valuable as current earnings, we have calculated the economic burden which must be added to medical costs. Using a very conservative estimate of $9,000 per year in economic production, the present value of future income for those patients who will be diagnosed with breast cancer this year will be almost $400 million.

Thus for breast cancer, putting aside the human ravages of the disease, the potential cost saving that could be accomplished by early detection and therefore potential curability could exceed $600 million dollars annually.

It is for these reasons that I urge your support for H.R. 1402 which will provide Medicare payments for such cancer prevention activities as screening mammography. It will hopefully also serve as a guideline for the private sector third party payers. Breast cancer will strike one in 11 women in the United States in their lifetime. In 1985, 110 women will die every day from this disease. These lives can and must be saved, and these women spared the scourge of breast cancer. H.R. 1402 takes a very significant step in this direction.

Sincerely,

Dr. MARVIN A. RICH.

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Listing of Cancer Centers Supported by the National Cancer Institute, National Institutes of Health

ALABAMA

Dr. Albert F. LoBuglio*
Director, Comprehensive Cancer Center
University of Alabama in Birmingham
University Station
1824 Sixth Avenue, S., Room 214
Birmingham, AL 35294
TEL: 205/934-5077

ALASKA
ARIZONA

Dr. Sydney E. Salmon**
Director, Arizona Cancer Center
University of Arizona
College of Medicine
1501 N. Campbell Avenue, Room 7925
Tucson, AZ 85724
TEL: 602/626-6044/7925

ARKANSAS
CALIFORNIA

Dr. Brian E. Henderson*
Director, Kenneth Norris, Jr.
Cancer Research Institute
University of Southern California
Comprehensive Cancer Center
P.O. Box 33804
1441 Eastlake Avenue
Los Angeles, CA 90033-0804
TEL: 213/224-6416

Dr. Richard J. Steckel*
Director, Jonsson Comprehensive
Cancer Center
UCLA Medical Center, Room 10/247
Louis Factor Health Sciences Building
10833 Le Conte Avenue
Los Angeles, CA 90024
TEL: 213/825-1532/5268

Dr. Saul A. Rosenberg**
Director
Northern California Cancer Program
1801 Page Mill Road
Building B, Suite 200
P.O. Box 10144
Palo Alto, CA 94303
TEL: 415/497-7431

Dr. William H. Fishman***
Director, Cancer Research Center
Cancer Research Center
La Jolla Cancer Research Foundation
10901 North Torrey Pines Road
La Jolla, CA 92037
TEL: 619/455-6480

Dr. Mark R. Green**
Acting Director, UCSD Cancer Center
University of California at San Diego
School of Medicine, T-010
La Jolla, CA 92093
TEL: 619/294-6178/6930

Dr. Charles Mittman**
Director, Cancer Research Center
Beckman Research Institute
City of Hope
1450 East Duarte Road
Duarte, CA 91010
TEL: 818/357-9711, x 2705

Dr. Walter Eckhart***
Professor and Director
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Salk Institute
P.O. Box 85800
San Diego, CA 92138
TEL: 619/453-4100, x 386

Dr. Leroy E. Hood***
Director, Cancer Center
California Institute of Technology
Biology Division 156-29
Pasadena, CA 91125
TEL: 818/356-4951

COLORADO
CONNECTICUT

Dr. Alan C. Sartorelli*
Director
Yale University Comprehensive
Cancer Center, Scool of Medicine
333 Cedar Street, Room WWW 205
New Haven, CT 06510
TEL: 203/785-4095

DELAWARE

* Comprehensive Cancer Center (20)
** Clinical Cancer Center (17)
*** Laboratory Cancer Center/Basic (16)
Number of Core Grants: 57

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DISTRICT OF COLUMBIA
Georgetown Univ./Howard Univ. Comprehensive Cancer Center

Dr. John F. Potter
Director, Vincent T. Lombardi Cancer Research Center
Georgetown University Medical Center
3800 Reservoir Road, N.W.
Washington, DC 20007
TEL: 202/625-2042

Dr. Jack E. White
Director, Cancer Research Center
Howard University Hospital
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FLORIDA

Dr. C. Gordon Zubrod, Director*
Papanicolaou Comprehensive Cancer Center
University of Miami Medical School
1475 N.W. 12th Avenue
P.O. Box 016960 (D8-4)
Miami, FL 33101
TEL: 305/548-4810

GEORGIA
HAWAII

Dr. Laurence N. Kolonel**
Acting Director, Cancer Research Center of Hawaii
University of Hawaii at Manoa
1236 Lauhala Street
Honolulu, HI 96813
TEL: 808/548-8415/8416

IDAHO
ILLINOIS
Illinois Cancer Council*
(Includes institutions listed & several other hlth. organizations)

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Dr. Nathaniel I. Berlin
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Health Sciences Building
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Dr. John E. Ultmann
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INDIANA

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Purdue University, Stadium Mall
Pharmacy Building, Room 506
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IOWA
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Dr. Phillip A. Sharp***
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Massachusetts Institute of
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MICHIGAN

Dr. Michael J. Brennan*
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MINNESOTA

Dr. Charles G. Moertel*
Director, Mayo Comprehensive
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Mayo Clinic
200 First Street, S.W.
Rochester, MN 55905
TEL: 507/284-2511

MISSISSIPPI
MISSOURI
MONTANA

NEBRASKA

Dr. Edward Bresnick***
Director and Eppley Professor of
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Eppley Institute for Research in Cancer
University of Nebraska Medical Center
42nd and Dewey Avenue
Omaha, NE 68105
TEL: 402/559-4238

NEVADA
NEW HAMPSHIRE

Dr. O. Ross McIntyre**
Director, Norris Cotton Cancer Center
Dartmouth-Hitchcock Medical Center
Hanover, NH 03755
TEL: 603/646-5505

NEW JERSEY
NEW MEXICO
NEW YORK

Dr. Paul Marks*
President
Memorial Sloan-Kettering Cancer
Center
1275 York Avenue
New York, NY 10021
TEL: 212/794-6561

Dr. James F. Holland**
Chairman, Department of Neoplastic
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Mt. Sinai School of Medicine
Fifth Avenue at 100th Street
New York, NY 10029
TEL: 212/650-6361

Dr. Gerald P. Murphy*
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666 Elm Street
Buffalo, NY 14263
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Dr. Enrico Mihich***
Director, Grace Cancer Drug Center
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Dr. I. Bernard Weinstein*
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POST-HEARING STATEMENT

of the

AMERICAN NURSES' ASSOCIATION

on

THE NEED FOR BREAST CANCER SCREENING PROGRAMS

AND

PATIENT EDUCATION

before the

SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

U.S. HOUSE OF REPRESENTATIVES

SELECT COMMITTEE ON AGING

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The American Nurses' Association (ANA), which represents the nation's 1.7 million registered nurses - the nation's largest group of health care professionals, is pleased to have the opportunity to submit this statement to the U. S. House of Representatives' Select Committee on Aging. As health care professionals, and as an overwhelmingly female profession, we firmly believe in the necessity of good breast cancer screening programs and of knowledgeable patients who can make well-informed decisions.

Few diseases carry with them the level of fear, of sheer terror that breast cancer does for most women. Too often that fear leaves women immobilized and intimidated, unable to act and to make wise decisions. We need more public information, encouraging women to seek early diagnosis and treatment; when they seek treatment, we need to be sure that women will be provided with adequate information to make an informed decision.

Our testimony will talk about the role nurses play in educating patients so that women have the necessary knowledge and skills to actively participate in screening and are informed health care consumers when they are in need of diagnostic tests or treatment. There is a special role that nurses can and should play in health care-teaching self-examination, and informing women about alternative treatments.

An example of how well nurses can meet the needs of women, particularly in screening, is evidenced by The Breast Lesion Evaluation Project at the Oncology Clinic of the Johns Hopkins University in Baltimore, Maryland. The

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clinic is headed by Patty Wilcox, a nurse practitioner, and staffed by two nurse clinical specialists and a staff nurse. This clinic has worked with women with cancer for many years. The Breast Lesion Evaluation Project focuses on early discovery of new lumps. The clinic staff discovered that there were two difficult periods for women psychologically facing breast cancer - the period of time from discovering the lump until the diagnosis was made and then two to three months after a mastectomy was performed. While there were facilities to help women once they had mastectomies, there really was none in the Baltimore area to help those women who had found a lump and didn't know where to turn. The project emphasizes screening to determine whether the women needs additional tests, treatment for a benign condition or to continue monitoring her condition on her own and practice routine breast self-examination. The clinic now serves women with any kind of breast complaint and has grown from 200 patients in the first year to 450 now.

Each patient in the clinic fills out a complete medical history on her general health as well as the specific complaint that brought her to the clinic. She is seen by a nurse, examined, and then given an assessment of the complaint. In addition, all patients participate in a breast self-examination class, in which they see a video tape, receive a brochure and are given a demonstration on how breast self-examination is done. Throughout the visit to the clinic, women are encouraged to ask questions and the nurses spend as much time with each patient as she needs. Of the patients seen at the clinic - 1/3 need further surgical evaluation, 1/2 need diagnostic tests like mammography, and the rest need to be reassured that their breasts are normal. The project has a low breast cancer detection rate of 5%, partially because women feel comfortable coming in with symptoms that they might be afraid to take to a physician, and because they come in early.

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The clinic's staff has a good working relationship with the medical community, and arranges for the appropriate diagnostic tests when a woman does not have her own physician. Most physicians like dealing with patients who have been through the clinic because they are patients who need a physician's care and because they are better educated and better prepared to deal with the rest of the tests or treatment. When a patient is referred to a radiologist for a mammogram, she calls the clinic for her results; which allows the staff additional time for discussion. The staff tries very hard to supply the patients with as much information as possible, and to encourage them to monitor their own health, teaching them what changes and symptoms to look out for.

Fifty percent of the women seen at the clinic are referred by a friend or self-referrals. An additional 30% are referred by a health clinic. Many women find it easier to be seen at the clinic than by a surgeon or a gynecologist. Their average age is 31, though the ages range from 13 to 78; 1/2 of them have used an oral contraceptive; 60% are black, 40% are white; 85% of them come from the greater Baltimore area.

The project has been an outstanding success and today its greatest problem is that it is held only once a week.

The clinic is but one example of the leading role nursing can play in educating women about breast cancer and its prevention, and how effective a screening program can be, both for the patients and for the health care community. The Breast Lump Evaluation Project delivers high quality health care efficiently, and effectively.

We urge passage of informed concent legislation so that no woman makes a life and death decision without adequate information. The need for informed consent was brought home to us by the experience of one of our members, a

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nurse-educator with a Ph D. who has faced breast cancer and surgery twice. With far more information than most women about breast cancer and its threat, and the risks of various types of treatment following surgery, this nurse, whom we'll call Dr. Hammond, found herself terrified and unable to evaluate the various alternatives when the diagnosis of breast cancer was made. But Dr. Hammond also found that she was not given a great deal of information about the alternatives nor really given the opportunity to make a decision. Prior to having her first surgery, Dr. Hammond asked the surgeon for a second opinion. Rather than giving her the name of another surgeon, the doctor gave her the name of a chemotherapist, and pushed to have the surgery. It was not until the day surgery was scheduled that she realized she had never really received a second opinion which she then insisted upon.

Even with a second opinion, Dr. Hammond felt that she was far from fully informed as to her alternatives and what the results of the treatment following surgery might be. She never had the information about what each surgical procedure involved - which procedures were mutilating, which ones made reconstruction impossible; how debilitating chemotherapy might be, or what the side effects were to it and radiation; and most importantly, what risks are associated with each alternative, and what the cure rates are for each.

Dr. Hammond believes that too often physicians think they are making it easier for their patient by ruling out choices. Doctors sometimes feel that at a critical time patients need protection rather than the right to make an informed decision. In addition, explaining and teaching takes a great deal of time, and training, and many physicians are unwilling and perhaps unable to do that. The logical person to handle this part of patient care is a nurse, who

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has the information, who is trained to educate patients and their families, and who understands that a factor in the survival rate is how well the patient can handle the symptoms and side effects of the disease and treatment. (The American Cancer Society and other organizations produce excellent materials which could be used all over the country to provide patients with basic information, which coupled with education from health care professionals, particularly nurses, would allow every woman to make an informed and carefully reasoned decision as to which treatment is best for her, her health, and her family.)

ANA believes that funding of breast cancer screening under Medicare, especially if it included reimbursement for nurse run and staffed screening programs, could help reduce the incidence of breast cancer related deaths, the leading cause of cancer deaths among women. When such programs include strong educational components on the need for breast self-examination, like the Hopkins' program, they increase drastically the possibility of spotting the cancer early. While regular examination by all primary care givers is important, an annual or semi-annual examination by a physician or nurse, or a bi-annual or annual mammogram, can not measure up to a monthly self-examination for the likelihood of spotting a lump early.

Good breast cancer screening programs and informed consent legislation are an important step towards the quality of health care we as a nation deserve and need.

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